UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

SUBHASH PATEL, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. KONINKLIJKE PHILIPS N.V., FRANS VAN HOUTEN, ABHIJIT BHATTACHARYA, and JOHN FRANK, Defendants.	Case No. 1:21-cv-04606-MKB-MMH SECOND AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS JURY TRIAL DEMANDED

TABLE OF CONTENTS

Lead Plaintiff Richard Sun and Plaintiff Subhash Patel ("Plaintiffs"), individually and on behalf of all others similarly situated, by Plaintiffs' undersigned attorneys, for Plaintiffs' complaint against Defendants (defined below), allege the following based upon personal knowledge as to Plaintiffs and Plaintiffs' own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiffs' attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Koninklijke Philips N.V. ("Philips" or the "Company"), communications with former employees, analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Philips securities between February 23, 2016 and November 1, 2022, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), *codified as amended*, 15 U.S.C. §§ 78j(b), 78t(a), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5, against the Company and two of its top officials.

2. Throughout the Class Period, Philips manufactured several popular Bi-Level Positive Airway Pressure ("BiPAP"), Continuous Positive Airway Pressure (CPAP), and mechanical ventilator devices. Many of these devices utilized polyester-based polyurethane (PE-PUR) foam (the "Foam") for sound abatement purposes.

3. These devices are life-saving for many. Throughout the Class Period, Philips sold millions of these devices, all the while touting their safety.

4. However, there was a problem known to Defendants, but undisclosed to the public. The Foam that was in these devices could degrade. Once the Foam degraded, it could break up into particles, which then could enter a device's air pathway and be ingested or inhaled by the user. The degrading Foam could also "off-gas certain chemicals" that are known to cause headache, dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea, vomiting, and that possess other toxic properties with carcinogenic effects.

5. By the end of 2015 at the latest, Philips had received multiple complaints about the Foam degradation. Many of the complaints came from users who detected the presence of black debris or particles within the airpath of their machines. Philips later admitted it had received reports of headache, upper airway irritation, cough, chest pressure and sinus infection associated with use of devices with Foam from consumers. Philips even emailed the supplier of the Foam about the issue, yet the Company failed to warn the public at large.

6. Over the years, complaints kept pouring into Philips. And Philips generated internal reports related to these complaints – reports that documented types of harm that could be caused by the Foam degrading. Philips did not share these reports with the public, however. The Company also did not adequately address any of the issues raised in these reports. For the most part – with the possible exception of a part replacement to one type of marketed device (a procedure not reported to the U.S. Food and Drug Administration ("FDA"), as required) – Philips kept all devices utilizing the Foam on the market without any changes.

7. Before mid-2021, Philips never disclosed to the public there was any issue with the Foam in its BiPAP, CPAP, and mechanical ventilator devices. It stated repeatedly it was

complying with all FDA regulations. It also promoted its products as safe, despite knowing otherwise.

8. Philips not only continued to tout the products with Foam that were already on the market, but it put new products containing the Foam on the market. At the height of the pandemic, it even received emergency authorization from the FDA, the regulatory body overseeing this type of product, for a ventilator that contained this Foam, without disclosing this defect to the regulator. This same ventilator, the E30, was among the products that would need to be recalled less than fourteen months later.

9. On April 26, 2021, as part of its Quarterly Report for Q1 2021, released well before the market closed, Philips disclosed for the first time, under a section entitled "Regulatory Update," that device user reports had led to the discovery that the Foam posed health risks to its users. Specifically, Philips disclosed that "the [PE-PUR] foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone[], and certain environmental conditions involving high humidity and temperature." A reserve of EUR 250 million was taken solely for repair of units in the field. If the devices were not repaired, the Foam could get caught in airways, possibly causing these life-saving devices to fail; additionally, users could ingest the Foam or ingest carcinogenic chemicals emitted from the Foam as it degrades.

10. The same day, the Company stated "[t]he majority of the affected devices are in the first-generation DreamStation product family" and mentioned no other product.

11. On this news – which did not inform the market of the full extent of the issues plaguing its devices – Philips' stock price fell $2.32 per share, or 3.8%, to close at $58.78 per share on April 26, 2021.

12. Then, on June 14, 2021, another shoe dropped. Philips issued a major recall of 20 products, including some of its popular sleep apnea DreamStation products and the E30 (in totality, the "Devices"). Philips had sold millions of the recalled Devices.

13. These were the Devices Philips recalled, but the Company did not indicate why it was only these products that were selected. Defendants stressed the recall was voluntary and proactive. Defendants sought to spin the recall as something that had occurred because of recent testing, as opposed to long-standing customer complaints. Van Houten, CEO of Philips, was quoted in the release as saying: "In consultation with the relevant regulatory agencies and in close collaboration with our customers and partners, we are working hard towards a resolution, which includes the deployment of the updated instructions for use and a comprehensive repair and replacement program for the affected devices. Patient safety is at the heart of everything we do at Philips."

14. On news of the recall, Philips' stock price fell $2.25 per share, or 3.98%, to close at $54.25 per share on June 14, 2021.

15. On July 22, 2021, the FDA identified this as a Class I recall, the most serious type of recall. According to the FDA website, FDA Class I recalls are only identified in "a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."

16. On July 26, 2021, as part of the release of its second quarter 2021 earnings, Philips reported it would need to take an additional EUR 250 million reserve, for a total of EUR 500 million, to account for the recall. It also would not be taking new sleep system orders during the period in which it needed to repair and/or replace the impacted units. On a related July 26, 2021 earnings call, van Houten signaled just how much of a loss this recall was for the Company, noting

that even before COVID-19 ("COVID") (when sales increased), "[t]he Sleep business is €1.1 billion, of which approximately 60% is systems, and 40% is masks and consumables. So then you can do your math and take out 60% of the systems as lost revenue."

17. On this news, the stock fell $1.80 per share, or 3.75%, from a close of $47.94 on July 23, 2021 to a close of $46.14 on July 26, 2021.

18. But it was not until November 2021 that the market truly discovered the reality of the situation. Philips had been burying complaints for years – from its users, from the market at large and even from the FDA.

19. On November 12, 2021, the FDA took the unusual step of reporting lengthy findings of its site investigation of Philips Respironics ("FDA Form 483"). FDA Form 483 documents years of malfeasance by Philips and, additionally, the inadequacy of even the recall and the reported replacement procedures. In the FDA Form 483 there were multiple damning observations about Philips.

20. In broad strokes, as detailed more fully below, the FDA site inspector made eight overarching observations.

21. Observation 1 was that Philips' "risk analysis is inadequate" because the Company did not properly document why some Devices were being recalled and not others; received several complaints beginning no later than 2015; and simply did not perform the proper analyses related to any risk posed by the Foam degradation—including not instituting a formal investigation until June 2019.

22. Observation 2 noted that Philips had not established proper procedures for corrective and preventive action, and it seemed that Philips was just handling matters (or not handling matters) as it suited the Company.

23. With Observation 3, the FDA Form 483 took Philips to task because the limited analysis the Company did conduct about Foam degradation was performed as if the Devices were used by people with healthy lungs and bodily functions, which is not usually the case.

24. Additionally, with Observation 4, the Company said even the selective corrections that Philips had developed (after years of ignoring the issue) "were not adequately verified, reviewed, or validated before implementation."

25. Observation 5 centered on the fact that Philips had not reported to the FDA, as required, a corrective field action on Trilogy ventilator devices that it had announced internally in 2018.

26. Observation 6 explained that Philips' management was aware of the Foam degradation issues and failed to properly remedy these issues. Here, the FDA noted that the issues were discussed at several meetings attended by executives. Yet Philips continued to leave their potential harmful products in the marketplace – even touting them repeatedly during the pandemic.

27. Observations 7 and 8 both focused on different aspects of Philips' failed quality control procedures. With Observation 7, FDA Form 483 focused on the fact that Philips had no documentation that established quality requirements regarding the Foam. With Observation 8, FDA Form 483 focused on the fact that potential consultants were not properly evaluated and selected based on their qualifications.

28. The FDA discovered years of complaints that Philips simply did not adequately address nor disclose. A search of Philips' internal database of consumer complaints performed as part of the FDA site inspection resulted in over 222,000 complaints that used keywords relevant to the Foam degradation issue. The FDA also found emails and reports where Philips acknowledged the issue, but, yet, nothing was done to correct it. The FDA even questioned the

safety of the silicone foam which was at the center of the "repair and replace" program associated with the recall.

29. On the news of Philips' longstanding coverup, and the possible ineffectiveness of its replacement plan, Philips' stock price fell $5.46 per share, or 11.5%, to close at $42.16 per share on Monday, November 15, 2021.

30. Defendants promoted their products as safe – and, indeed, continue to develop new products during the Class Period utilizing the Foam – but they knew differently. Plaintiffs and the Class were plainly damaged by Defendants' fraud.

31. On January 26, 2022, the FDA classified the recall of Philips' Trilogy Evo ventilators as a Class I recall, the most serious type of recall.

32. On this news, Philips' stock price fell $0.96 per share, or 2.90%, to close at $32.20 per share on January 26, 2022.

33. On February 14, 2022, Connecticut's U.S. Senator Richard Blumenthal and Attorney General William Tong sent a letter to the FDA's Commissioner stating that "Connecticut constituents have expressed alarm that the FDA and Philips have failed to put in place a transparent plan to mitigate the now-clear carcinogenic risks associated with these devices, despite multiple warnings to consumers." Senator Blumenthal also tweeted: "Philips' breathing machine recall process has been a deeply inadequate, life threatening failure. I join @AGWilliamTong to demand the FDA act swiftly to hold Philips accountable [and] protect the millions of Americans [and] thousands of CT residents impacted by this recall."

34. On this news, Philips' stock price fell $0.63 per share, or 1.87%, to close at $33.03 per share on February 14, 2022.

35. On March 10, 2022, the FDA issued a notification order to Philips Respironics requiring the company to notify patients and others of the June 14, 2021 recall. The FDA explained that it "has determined that this order is necessary to eliminate the unreasonable risk of harm posed by the recalled products, because the company's notification efforts to date have been inadequate."

36. On this news, Philips' stock price fell $0.61 per share, or 1.93%, to close at $31.02 per share on March 10, 2022.

37. On April 25, 2022, Philips announced that Philips Respironics and other unnamed Philips subsidiaries in the U.S. received a subpoena on April 8, 2022 from the U.S. Department of Justice ("DOJ"), seeking "information related to events leading to the Respironics [foam] recall." Philips also stated that it would be allocating another €215m for the recall field action provision.

38. On this news, Philips' stock price fell $3.43 per share, or 11.3%, to close at $26.91 per share on April 25, 2022.

39. On June 28, 2022, Philips' shares dropped approximately 3.18%, to close at $21.29 per share on June 28, 2022, after analysts from UBS said on that day that tests from the Company's first-generation DreamStation devices were not reassuring to the market. Citing the failure of two cytotoxicity tests, UBS called it a "'disappointing testing update' and not the 'unequivocal' positive news investors were hoping for."

40. On July 25, 2022, Philips stated that the DOJ, acting on behalf of the FDA, provided a proposed consent decree after the FDA's inspection of Philips Respironics facilities in 2021. While the terms of the proposed consent decree were not disclosed, Wall Street analysts were already weighing in on the DOJ news, arguing that it will likely boost rival ResMed, if the FDA temporarily shuts Philips' manufacturing. "The consent decree could lead to production being stopped at [Philips] facilities while it resolves its quality issues, causing further delays in re-

entering the market," Needham analysts wrote in a Monday note. Analysts with KeyBanc Capital Markets wrote that a consent decree "would present additional uncertainty to its ability to fully return to new patient diagnosis."

41. On this news, Philips' stock price fell $1.59 per share, or 7.18%, to close at $20.55 per share on July 25, 2022.

42. On August 16, 2022, the FDA updated its safety communication concerning the breakdown of the Foam in the recalled Devices. Since April 2021, the FDA has received more than 69,000 medical device reports ("MDRs"), including 168 reports of death, associated with the Foam breakdown or suspected Foam breakdown. Philips also announced that effective October 15, 2022, Roy Jakobs will be appointed as Philips' CEO to replace van Houten.

43. On this news, Philips' stock price fell $1.11 per share, or 5.4%, to close at $19.48 per share on August 17, 2022.

44. On October 12, 2022, Philips stated it was negotiating with the DOJ over a final settlement on the Philips' foam respiratory Device recall. Philips stated that it "expects to record a 1.3 billion euro [$1.26 billion] non-cash charge in the third quarter for the impairment of goodwill of its sleep and respiratory care business" and that its sales declined approximately 5%.

45. On this news, on October 12, 2022, Philips' stock price fell to its lowest level since June 2012, $1.74 per share, or 11.7%, to close at $13.17 per share on October 12, 2022.

46. On October 24, 2022, Philips announced that it would cut 4,000 jobs (approximately 5% of its workforce) as part of a EU300 million cost savings package for the June 14, 2021 recall. A *Bloomberg* article stated "shares in Philips fall as much as 4%, to their lowest since 2011, after saying it would cut 4,000 jobs as part of a EU300 million cost savings package, which analysts say may imply liquidity problems for the Dutch medical technology firm."

47. On this news, Philips' stock price fell $0.18 per share, or 1.4%, to close at $12.89 per share on October 24, 2022.

48. On October 31, 2022, pre-market, J.P. Morgan issued an analyst report cutting and moving the price target for Philips as part of their "feedback, latest thoughts and model update" following the Company's investor meeting held on October 28. J.P. Morgan stated that "[t]here remain significant overhangs around litigation, supply chain, the macro outlook and their new mid-term outlook from a new CEO." J.P. Morgan explained that free cash flow was "being impacted by the high restructuring and recall costs," and that "[t]he company has flagged quality issues and supply chain disruptions as on-going concerns." As for biocompatibility study results, the analysts expressed disappointment in the unexpected delays of the outcomes from the testing studies, which "may increase investor nervousness."

49. On this news, Philips' stock price fell $0.45 per share, or 3.5%, to close at $12.58 per share on November 2, 2022. The next day, on November 3, 2022, Philips' stock price fell another $0.83 per share, or 6.6%, to close at $11.75 per share.

50. In total, tens of thousands of individuals using Philip's foam ventilators have alleged that they developed multiple types of cancers as a result of their use of the Devices, including Bladder Cancer, Brain Cancer, Breast Cancer, Kidney Cancer, Leukemia, Liver Cancer, Lung Cancer, Lymphatic Cancer, Multiple Myeloma, Papillary Carcinoma, non-Hodgkin lymphoma, Prostate Cancer, Stomach Cancer and Thyroid Cancer. The chemicals in the Foam include isocyanates, some of which are compounds classified as potential human carcinogens and known to cause cancer in animals, according to the Occupational Safety and Health Administration. They also cause asthma and lung problems and may have additional impact on the eyes, nose, throat and skin.

JURISDICTION AND VENUE

51. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

52. This Court has exclusive subject-matter jurisdiction of all claims asserted herein pursuant to Section 27 of the Exchange Act, *codified as amended*, 15 U.S.C. § 78aa (for violations of the Exchange Act), and original subject-matter jurisdiction of all claims asserted herein pursuant to 28 U.S.C. § 1331 (for all claims arising under federal law). The Court also has subject-matter jurisdiction pursuant to the Class Action Fairness Act, Pub. L. No. 109-2, 119 Stat. 4, *codified as amended*, 28 U.S.C. § 1332(d) because (1) the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs, (2) the action is a class action, (3) there are members of the proposed Class who are diverse from all Defendants, (4) on information and belief, at least one Defendant is a subject of the Kingdom of the Netherlands, and (5) there are more than 100 members in the proposed Class.

53. Venue is proper in this District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Pursuant to Philips' most recent Annual Report, as of December 31, 2021, there were 870,182,445 of the Company's common shares outstanding. Accordingly, there are presumably hundreds, if not thousands, of investors in Philips' securities located within the U.S., some of whom undoubtedly reside in this Judicial District. Philips' shares trade on the New York Stock Exchange ("NYSE"), which is located in this judicial district.

54. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mail, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

55. Lead Plaintiff Richard Sun, as set forth in his previously filed Certification, acquired Philips securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

56. As set forth in his previously filed Certification, Plaintiff Subhash Patel acquired Philips securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

57. Defendant Philips is organized under the laws of the Kingdom of the Netherlands, with principal executive offices located at Breitner Center, Amstelplein 2, 1096 BC Amsterdam, the Netherlands. The Company's common shares trade in an efficient market on the NYSE under the ticker symbol "PHG". The term "Philips" includes Philips Respironics, Inc. a/k/a Respironics, Inc. ("Philips Respironics"), a Delaware corporation, n/k/a Philips RS North America LLC, a Delaware limited liability company, whose principal offices are and were located at 6501 Living Place, Pittsburgh, Pennsylvania 15206, and which is, and at all relevant times was, a wholly owned subsidiary of Koninklijke Philips N.V. The term "Philips" also includes Philips North America LLC ("Philips NA"), a Delaware limited liability company with its principal offices located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141, which is, and at all relevant times was, a wholly owned subsidiary of Koninklijke Philips N.V.

58. Defendant François Adrianus "Frans" van Houten ("van Houten") has served as Philips' Chief Executive Officer and Chairman of the Board of Management and the Executive Committee at all relevant times.

59. Defendant Abhijit Bhattacharya ("Bhattacharya") has served as Philips' Chief Financial Officer since October 12, 2015, as a Member of the Board of Management since December 18, 2015, and as a Member of the Executive Committee at all relevant times.

60. Defendant John Frank ("Frank") served as the Chief Executive Officer at Philips Sleep and Respiratory Care and was on Philips' Executive Committee at all relevant times.

61. Defendants van Houten, Bhattacharya, and Frank are sometimes referred to herein as the "Individual Defendants."

62. The Court has personal jurisdiction over the Individual Defendants because the Individual Defendants conducted substantial business in this District, and the events giving rise to Plaintiffs' claims arise out of and relate to the Individual Defendants' contacts with this District. The Individual Defendants' actions are controlled by Philips. The Individual Defendants' affiliations with this District are so continuous and systematic as to render them essentially at home in New York. Further, the Individual Defendants have transacted business, maintained substantial contacts, purposefully targeted investors, and committed other overt acts in furtherance of the unlawful acts alleged herein in this District, as well as throughout the United States. The unlawful acts of the Individual Defendants have been directed at, have targeted, and have had the effect of causing injury to investors who are citizens or nationals of the United States, and to investors who reside in, are located in, or are doing business in this District, as well as throughout the United States, and who purchased their shares of Philips securities on the NYSE located in this District.

63. The Individual Defendants possessed the power and authority to control the contents of Philips' SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Philips' SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Philips, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed

from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

64. Philips and the Individual Defendants are collectively referred to herein as "Defendants."

THE CONFIDENTIAL WITNESSES

65. Confidential witness ("CW") 1 was a Vice President of Sales at Philips' U.S. Sleep and Home Respiratory division from 2008 to 2019. CW1's supervisor reported to Mark D'Angelo (Sleep Business Leader for Philips Sleep and Respiratory Care, who ran the CPAP product) and Eli Diacopoulos (VP General Manager at Philips Respironics). D'Angelo and Diacopoulos reported to John Frank (Philips Group Leader for Sleep & Respiratory Care Business), who reported to van Houten.

66. CW2 was a Business Marketing Manager at Philips' Sleep and Respiratory Care division from 2006 to 2021. S/he helped launched the CPAP and BiPAP products.

SUBSTANTIVE ALLEGATIONS

Background

67. Philips operates as a health technology company in North America, Greater China, and internationally. On its website, Philips states its "purpose is to improve people's health and well-being through meaningful innovation." The Company makes everything from toothbrushes to baby bottles to car lights and, as relevant to this litigation, sleep and respiratory care products.

68. At all relevant times, Philips used the means and instrumentalities of interstate commerce in the United States to design, manufacture, market to U.S. consumers, sell to U.S. consumers, distribute to U.S. consumers, and profit from U.S. consumers, certain CPAP, BiPAP, and mechanical ventilators, that Philips represented to investors were for the purpose of assisting

individuals with a number of sleep, breathing, and respiratory conditions, including obstructive sleep apnea, central sleep apnea, complex sleep apnea syndrome, and Chronic Obstructive Pulmonary Disease (COPD), as well as to assist those individuals requiring invasive and non-invasive ventilators for acute and sub-acute hospital environments.

69. Sleep apnea is a common sleep disorder characterized by repeated interruptions in breathing throughout an individual's sleep cycle. These interruptions, called "apneas," are caused when the soft tissue in an individual's airway collapses. The airway collapse prevents oxygen from reaching the individual's lungs which can cause a buildup of carbon dioxide. If the individual's brain senses the buildup of carbon dioxide, the individual will rouse briefly from sleep so that the individual's airways can reopen to restore the flow of oxygen. Often, these interruptions are brief and individuals do not remember waking. Despite the brevity of the interruptions in oxygen flow, the sleep cycle disruption caused by sleep apnea can dramatically impact a person's lifestyle, including negatively impacting energy, mental performance, and long-term health.

70. CPAP therapy is a common nonsurgical treatment primarily used to treat sleep apnea, and typically involves the use of a nasal or facemask device that helps an individual to breathe by increasing the air pressure in the throat. BiPAP therapy is a common alternative to CPAP therapy in the treatment of sleep apnea. BiPAP therapy is a nonsurgical treatment that involves using a nasal or facemask device to maintain air pressure in an individual's airways. BiPAP therapy delivers two alternating levels (*i.e.*, inspiratory and expiratory) of pressurized air into an individual's airway, delivering one level of pressurized air to assist as a person inhales, and another level to assist in exhaling. Mechanical ventilators are used to help an individual to breathe when a patient cannot breathe autonomously, or when breathing autonomously is extremely difficult. Mechanical ventilators push airflow into a patient's lungs to assist with breathing.

Mechanical ventilation may be invasive (*i.e.*, with a tube inserted into an individual's airway by a medical professional in an inpatient setting) or non-invasive (*i.e.*, a patient can connect the device at home without assistance of a medical professional).

71. Without medical insurance, Philips' CPAP, BiPAP, and mechanical ventilator devices typically cost tens of thousands of dollars; with medical insurance, the devices cost several hundred, if not thousands, of dollars. Philips sold millions of these devices in the United States during the Class Period.

72. The Devices marketed and sold in the United States must adhere to the statutory framework set forth in the Federal Food, Drug, and Cosmetic Act (the "FDCA"), Pub. L. No. 75-717, 52 Stat. 1040 (June 25, 1938), *codified as amended*, 21 U.S.C.S. §§ 301 *et seq.*, which governs the movement in interstate commerce of food, drugs, devices, and cosmetics. In particular, the Devices were subject to the duly-promulgated regulations and reporting requirements of the FDA at all relevant times.

73. Each of the Devices is or was a "device" within the meaning of Section 321(h)(1) of the FDCA (21 U.S.C.S. § 321(h)(1)), because each is or was "an instrument, apparatus, implement, machine, contrivance, . . . or other similar or related article, including any component, part, or accessory," that is or was "recognized in the National Formulary, or the United States Pharmacopeia" or its supplements, was "intended for use in the . . . cure, mitigation, treatment, or prevention of disease, in man or other animals," or is or was "intended to affect the structure or any function of the body of man or other animals," and does or did "not achieve its primary intended purposes through chemical action within or on the body of man or other animals" and is or was "not dependent upon being metabolized for the achievement of its primary intended purposes." *Id.*

74. Each year, and periodically, Philips was required to register each of the Devices with the FDA, and to comply with all other duly promulgated regulations issued by the FDA, pursuant to Section 360 of the FDCA (21 U.S.C.S. § 360).

75. Each of the Devices was subject to premarket approval by the FDA, pursuant to Section 360(k) of the FDCA (21 U.S.C.S. § 360(k)). Each of the Devices received such approval.

76. Each of the Devices was subject to classification by the FDA, pursuant to Sections 360c–e of the FDCA (21 U.S.C.S. §§ 360c–e).

77. Each of the Devices was subject to "performance standards" set by the FDA "to provide reasonable assurance of the safety and effectiveness of the device," pursuant to Section 360(d) of the FDCA (21 U.S.C.S. § 360d).

78. At all relevant times, Philips was a "manufacturer" of the Devices because it "manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. 21 C.F.R. § 803.3(*l*). Specifically, Philips repackaged or otherwise changed "the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture," initiated "specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications," manufactured "components or accessories that are devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient," and/or was "the U.S. agent of a foreign manufacturer." *Id.* § 803.3(l)(1)–(4).

79. Each of the Devices was subject to certain annual, post-approval reporting requirements. For each Device, Philips was required to submit an annual report to the FDA

certifying the Company was engaged in, among other things, the "[c]ontinuing evaluation of the safety effectiveness, and reliability of the device for its intended use." 21 C.F.R. § 814.82(a)(2).

80. Each of the Devices was subject to certain periodic post-approval reporting requirements. In each such periodic report, Philips was required, among other things, to submit "[u]npublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices," "[r]eports in the scientific literature concerning the device," and "[c]hanges in the performance . . . of the device." 21 C.F.R. § 814.84(b); id. § 814.39(a)(6).

81. Each of the Devices was also subject to further reporting requirements with respect to certain adverse events or product problems. Specifically, for each Device, Philips was obligated to report to the FDA, "no later than 30 calendar days after the day that [Philips] receive[d] or otherwise bec[a]me aware of information, from any source, that reasonably suggests that a device" either "[m]ay have caused or contributed to a death or serious injury" or "[h]as malfunctioned and this device or a similar device [marketed by Philips] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." 21 C.F.R. § 803.50(a).

82. A "[m]alfunction means the failure of a device to meet its performance specifications or otherwise perform as intended." *See* Final Rule, *Medical Device Reporting: Electronic Submission Requirements*, 79 Fed. Reg. 8,832, 8,847 (Dep't Health & Hum. Servs., Food & Drug Admin. Feb. 14, 2014) (codified at 21 C.F.R. § 803.3(k)).

83. A "[s]erious injury means an injury or illness that: (1) [i]s life threatening, (2) [r]esults in permanent impairment of a body function or permanent damage to a body structure, or (3) [n]ecessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Permanent means irreversible impairment or

damage to a body structure or function, excluding trivial impairment or damage." Final Rule, 79 Fed. Reg. at 8,848 (codified at 21 C.F.R. § 803.3(w)).

84. As part of its regulatory requirements, Philips needed to establish Corrective and Preventive Action (CAPA) programs. In simple terms, the government mandates that each manufacturer "establish and maintain procedures for implementing corrective and preventive action." 21 C.F.R. § 820.100.

85. In plain language, a CAPA program is a well-documented system with two components: the corrective portion identifies the root cause of non-conformances, system failures, and other problems; the preventive portion is designed to ensure that the problems do not occur in the first place (or do not reoccur after identification in the corrective portion). According to the FDA's website, "The purpose of the corrective and preventive action subsystem is to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence." According to the FDA: "One of the most important quality system elements is the corrective and preventive action subsystem."

86. The Company itself is responsible for establishing a CAPA program in accordance with the CAPA Regulation; the FDA does not police compliance.

87. Each of the Devices was also subject to the FDA's Quality System Regulation, as set forth in part 820 of Title 21 of the Code of Federal Regulations. *See generally* 21 C.F.R. § 820.1–.250.

88. Specifically, "[***m***]***anagement with executive responsibility***" was required to "establish [the Company's] policy and objectives for, and commitment to, quality," and "[m]anagement with executive responsibility" was required to "ensure that the quality policy is

understood, implemented, and maintained at all levels of the organization." 21 C.F.R. § 820.20(a) (emphasis added). Further, "[m]anagement with executive responsibility" was required to "review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the [FDA regulations] and [the Company's] established quality policy and objectives." *Id.* § 820.20(c). The Company was required to "establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established equality system requirements and to determine the effectiveness of the quality system." *Id.* § 820.22. "A report of the results of each quality audit, and reaudit(s) where taken, shall be made ***and such reports shall be reviewed by management having responsibility for the matters audited***. The dates and results of quality audits and reaudits shall be documented." *Id.* (emphasis added).

89. The Company was also required to "have sufficient personnel with the necessary education, background, training, and experience to assure that all activities [relating to quality system controls] are correctly performed." 21 C.F.R. § 820.25(a). The Company was also required to "establish and maintain procedures to control product that does not conform to specified requirements," addressing "the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented." *Id.* § 820.90(a). "Nonconformity means the nonfulfillment of a specified requirement." *Id.* § 820.3(q).

90. Philips also represented it was following guidance from the International Organization for Standardization ("ISO"). ISO 13485:2016: Medical devices — Quality

management systems — Requirements for regulatory purposes is a document that "specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements."

91. Therefore, under multiple regulations and guidance, Philips was required to have the mechanisms in place to identify and investigate product and quality defects and take corrective action. It was also required to report problems and corrective actions to the FDA in almost all relevant circumstances.

92. Defendants were well aware of these requirements. Indeed, the Company had a history of failing to comply with the FDA's quality systems regulations. For example, on October 31, 2017, the Company entered into a Consent Decree with the DOJ to resolve allegations that Philips sold certain other devices that the Company knew were, or knowingly caused to become, adulterated by, among other things, failing to maintain "current good manufacturing practice ('CGMP') requirements set forth in 21 C.F.R. Part 820." Consent Decree for Permanent Injunction, *United States v. Philips N. Am. LLC*, Case No. 17-CV-11955, ECF No. 10 ¶¶ 1–4 (D. Mass. filed Oct. 31, 2017).

Relevant Products

93. Many of the products in Philips' "Sleep and Respiratory Care" division were long industry leaders. The Devices were in the Sleep & Respiratory Care Division of Philips.

94. Specifically, the products that were subject to the recall are:

All Devices manufactured before 26 April 2021, All serial numbers	
Continuous Ventilator	Trilogy 100
	Trilogy 200
	Garbin Plus, Aeris, LifeVent

All Devices manufactured before 26 April 2021, All serial numbers	
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	E30 (Emergency Use Authorization)
	A-Series BiPAP V30 Auto
	A-Series BiPAP Hybrid A30 (not marketed in the U.S.)
Continuous Ventilator, Non-life Supporting	DreamStation ASV
	DreamStation ST, AVAPS
	SystemOne ASV4
	C-Series ASV
	C-Series S/T and AVAPS
	OmniLab Advanced+
	A-Series BiPAP A40
	A-Series BiPAP A30
Noncontinuous Ventilator	SystemOne (Q-Series)
	DreamStation
	DreamStation Go
	Dorma 400
	Dorma 500
	REMstar SE Auto

95. The Devices are among the Philips BiPAP, CPAP and mechanical ventilator Devices in the Philips product line that utilize the relevant Foam for sound abatement.

96. According to the Company, the Trilogy Devices "provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation" and are used for both home and hospital use. The earliest of them was approved for use in America by the FDA in 2009.

97. According to the Company, the DreamStation Devices are designed for the treatment of Obstructive Sleep Apnea and are used for both home and hospital use. Philips launched its DreamStation product line in October 2015. Philips' DreamStation products are among the best-selling CPAP machines on the market.

98. Each time one of the products in these lines came on the market, Philips touted its supremacy with no mention of negative reports on the Foam. For example, the DreamStation Go – designed with the same Foam the Company already knew was degrading – was launched in 2017. In an April 11, 2017 press release announcing the product's launch, the Company stated: "At half the size of Philips' previous generation devices, DreamStation Go delivers the same clinically-proven performance and comfort, for reliable, convenient therapy on-the-go. Designed with traveling patient needs in mind, DreamStation Go is the product of over 30 years of sleep therapy innovation."

99. The release further promoted the entire DreamStation production line: "DreamStation Go is the latest addition to Philips' award-winning Dream Family of sleep apnea products focused on connecting and supporting the patient, clinician, and homecare provider to enhance patient care and quality of life. Dream Family has impacted more than one million patient lives since launched in 2015."

100. In the midst of the COVID-19 pandemic, Philips obtained emergency use authorization from the FDA for a new product, a ventilator E30, which also utilized the Foam. Philips stated the Company was developing the product "with the needs of healthcare workers and COVID-19 patients in mind while also complying to medical device quality standards." According to the Philips' website: "This global ventilator solution, can be purchased by governments and hospitals who are experiencing ventilator shortages. The Philips Respironics E30 ventilator can be used when there is limited access to a fully featured critical care ventilator."

101. Other impacted products are similarly used for ventilation.

Philips Promotes Its Products as Safe Despite Knowledge of Defects

102. In each annual report during the Class Period, Philips stated in substance (though the exact words changed: "Philips actively maintains Quality Systems globally that establish

processes for its product design, manufacturing and distribution processes; these standards are in compliance with Food and Drug Administration (FDA)/International Organization for Standardization (ISO) requirements. Our businesses are subject to compliance with regulatory pre-marketing and quality system requirements in every market we serve, and to specific requirements of local and national regulatory authorities including the US FDA . . ." But Philips was not overly concerned with quality – it was manufacturing Devices with a foam that was breaking apart.

103. Philips "became aware of" the issue with polyester polyurethane foam degradation "and related field complaints in at least 2015 or earlier[.]"[1] According to the FDA, at least two of these complaints were from Trilogy 100 users and at least some others were from Trilogy 200 users. On October 20, 2015, Philips sent an email to its Foam supplier implying that a customer made Philips aware of polyester polyurethane foam degradation issues.

104. Then, according to the FDA, on or around November 15, 2015, Philips was made aware of a preventative maintenance servicing procedure implemented by another Philips entity in another country on Trilogy ventilator products, but did not conduct any "further investigation, health hazard evaluation, risk analysis, or design review . . . in response to foam degradation issues and complaints in the field related to Trilogy ventilator products." In other words, Philips did nothing in response to this news.

105. According to the FDA, Philips should have begun an investigation into these issues with the Foam, but it did not.

106. These degradation issues were extremely important as they can cause two serious issues, according to Philips' own later admissions. First, Philips was aware that the Foam may

[1] Unless otherwise specified, all quotes come from the FDA Form 483. When the Complaint states "According to the FDA," the information is coming from data the FDA made public in 2021. None of this was disclosed by Philips.

degrade into particles which enter the device's air pathway and be ingested or inhaled by the user. Second, Philips said the Foam may "off-gas certain chemicals" that may cause headache, dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea, vomiting, and/or have toxic and carcinogenic effects. In other words, products that people were using to save their lives could possibly cause cancer because of issues with this Foam.

107. None of the degradation issues was reported to the public. Additionally, none of the degradation issues triggered a CAPA, as would have been industry standard. Philips kept products with the Foam on the market and continued to manufacture, market, and sell new ones.

108. On February 23, 2016, after Philips became aware of the degradation issues, the Company issued its annual report for the fiscal year ended December 31, 2015 on SEC Form 20-F (the "2015 20-F") touting its commitment to "quality system requirements" and their compliance with FDA regulations, despite not instituting a CAPA when the Company became aware of the foam degradation issues. Nowhere in the Company's risks disclosures is a mention of any risk associated with the Foam or possible regulatory action as a result of the Foam.

109. A couple of months later, according to the FDA, an internal report by Philips dated April 1, 2016, which utilized field samples obtained in October 2015 from the Trilogy 100 ventilator, "document[ed] base polymer cleavage and embrittlement of the returned foam material of the related field samples." In other words, samples from Trilogy 100 ventilators being used by real people in the field clearly displayed the Foam was disintegrating and breaking. Philips had a written analysis in April 2016 that documented the issue.

110. On August 5, 2016, according to the FDA, Philips' foam supplier sent an email advising Philips that degradation of the Foam was "likely" and could occur somewhat quickly.

111. Still, a CAPA was not initiated and no design change was implemented. Moreover, investors were never alerted to these defects.

112. According to the FDA, another internal report, AST282T-161438, studied the Foam in the Company's Trilogy 200 ventilator in response to two "customer complaints from 2015" and found "bad resistance against high humidity in combination with high temperature."

113. Later in 2016, according to the FDA, Philips conducted yet another test showing problems with polyester urethane foams. Test Report AST 282T-161459, dated November 25, 2016, found that different types of foams showed significant resistance to degradation, but the polyester urethane foams did not perform well.

114. Philips could have potentially used one of those other foams in future products, and replaced the Foam in current products, but it did not do so. It did not report the findings of any of these test results to the FDA nor advise the investing public. It did not institute a CAPA to study these issues properly. Philips documented, and thus knew of, a way to mitigate the risks associated with the Foam and to help users of its products, but Defendants kept this information to themselves.

115. For the year ended 2016, sales from the Company's Sleep & Respiratory Care business accounted for 21% of all income from sales in the Personal Health segment. For the same year, the Company reported income from sales from Personal Health of €7,099,000 and Company-wide income from sales of €24,516,000.

116. From 2014 to 2017, according to the FDA, Philips received at least thirty complaints specifically related to the Trilogy ventilator Devices and eighty complaints related to degradation for the Foam on non-Trilogy ventilator Devices from 2014 to 2017. A later search of Philips' database disclosed over 175,000 complaints that came up in a keyword search for the terms contaminants, particles, foam, debris, airway, particulate, airpath, and black. Additionally,

according to the FDA, Philips also identified 110 complaints specifically related to foam degradation from 2014 to 2017.

117. However, Philips did not disclose any of this to the market, and its sales stayed strong. For the year ended 2017, sales from the Company's Sleep & Respiratory Care business accounted for 22% of all income from sales in the Personal Health segment. For the same year, the Company reported income from sales from Personal Health of €7,310,000 and Company-wide income from sales of €17,780,000.

118. On April 23, 2018, Bob Marsh from Polytech Inc., a/k/a Polymer Technologies, one of the entities that supplied the Foam to Philips, emailed Lee Lawler, the Technical and R&D Manager of William T. Burnett, a manufacturer of bulk foam that supplied foam to Polymer Technologies, regarding one of its customers—Philips—finding degradation of ester foam in their device. Mr. Marsh included with his email an April 20, 2018, email from Vince Testa, Project Mechanical Engineer at Philips Home Healthcare Solutions. On April 20, 2018, Mr. Testa emailed Bonnie Peterson at Polytech Inc., noting in the subject line of the email the issue of "PAFS Deterioration" and marking the email with "High" importance. In the email, Testa wrote that Philips "use[s] the PAFS foam in the air path of our Trilogy family of ventilators as a means for noise reduction" and has received complaints from customers that "the foam is disintegrating." Testa underscored that "[a]s you can imagine, this is not a good situation for our users." Testa added that he "flagged this message with high importance since we are addressing a potential safety concern."

119. In his April 23, 2018 email referenced above, Mr. Marsh referenced a prior email exchange he and Mr. Lawler had in August 2016 regarding Philips (the customer of Polymer Technologies), who observed foam degradation in one of their medical devices after five years of

use. Mr. Lawler responded to Mr. Marsh that "I would not be surprised if ester foam, continuously exposed to 40C (104F) at high humidity, would exhibit signs of hydrolysis in as short as a year. Intermittent exposure would extend the lifeline, but that is not a good environment for polyester foam." Mr. Marsh responded: "Thanks. I'll let them know they'd be better off with ether."[2]

120. Following up on his April 23, 2018 email, Mr. Marsh emailed Mr. Lawler on May 2, 2018, informing him that Philips "tested ether v. ester in high heat and humidity and found ether to be the better performer. It validated what we (you) conveyed."[3]

121. On May 3, 2018, Mr. Testa admitted to Mr. Marsh that "We are evaluating our options regarding the foam. We could switch to the PAF [ether-based foam], or we could indicate a preventative maintenance cycle in which they would replace the PAFS [ester-based] foam pieces. . . . The environmental conditions for our device are a maximum of 40C and 95% R.H. Note the difference in temperature."

122. Between May 2 and May 4, 2018, Mr. Lawler exchanged additional emails with Mr. Marsh, addressing questions he posed based on information he received from Philips. On May 4, 2018, Mr. Lawler responded to Mr. Marsh, against stating that "We would not recommend use of **polyester** foam in such an environment and have no direct data to use to calculate the rate of hydrolysis. **Polyether** foam lifetime would not be expected to reduce significantly at the stated conditions . . . Polyester foam will lose tensile strength and overall integrity as it hydrolyzes. It

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[2] *See* Affidavit of Lee Lawler and exhibits, filed in *In re: Philips Recalled CPAP, Bi-Level PAP, and Mechanical Ventilator Products Litigation*, 2-21-mc-01230-JFC, Dkt. No. 589-1 (W.D. Pa. 2021). In his affidavit, Mr. Lawler concluded that "Consistent with what I informed our customer, Polymer Technologies, in 2016 and 2018, if any Burnett polyester foam was used in an environment that subjected the foam to high heat and humidity, such foam was incorrect for that application." *Id*.

[3] *Id*.

will eventually decompose to a sticky powder. That will happen very rapidly at 40C, 95% R.H." (emphasis in the original). Mr. Marsh responded: "Thanks Lee. I appreciate the comments and perspective. Ill [sic] pass them on to the customer." [4]

123. According to the FDA, by 2018, only around 20,000 of the over 175,000 complaints that came up in a keyword search involved Trilogy Devices, meaning approximately 155,000 involved other Devices and included the keywords "contaminants, particles, foam, debris, airway, particulate, airpath, and black."

124. However, in April 2018, when Philips finally instituted a CAPA in response to field complaints about its Devices, it was only on Trilogy Devices and only an informal CAPA. According to the FDA, Philips' "process was to open CAPA requests, referred to as CAPA INVs, as a precursor to formal CAPAs, but would only be made into formal CAPAs, if approved by a CAPA Review Board, or delegate(s)." CAPA INV 0988 was opened on April 12, 2018, due to units returned from the field, where the foam was degrading and getting into the units' motor/air path. It was closed on June 20, 2018, and no formal CAPA was initiated or implemented.

125. According to the FDA, CAPA INV 0988 involved Trilogy 100 and 200 ventilator devices only and did not "include, investigate, or examine" all of the Philips medical devices with "similar air path assemblies and/or the affected polyester polyurethane foam, which is susceptible to degradation." This failure to act occurred despite the fact that, according to the FDA, before CAPA INV 0988 was instituted, Philips had received approximately eighty complaints related to foam degradation on non-Trilogy ventilator Devices. Yet Philips still chose not to even look at any Devices beyond Trilogy 100 and 200.

[4] *Id.*

126. According to the FDA, CAPA INV 0988 – more than the Company had done in prior years – was still woefully insufficient, as a Health Hazard Evaluation report associated with CAPA INV 0988 made clear. As FDA Form 483 stated: "Health Hazard Evaluation ER2227646 V06, approved and closed on 06/15/2018, related to CAPA INV 0988, and concerning Trilogy 100 and 200 ventilator devices, documents typical and healthy lung and bodily functions, and does not conform to or address the user needs of the intended patient population of these ventilatory medical devices. The intended patient population of Trilogy 100 and 200 ventilator devices are individuals requiring mechanical ventilation, that potentially lack typical and healthy lung and bodily functions considered in your HHE. Furthermore, Health Hazard Evaluation ER2227646 V06 does not consider patients with a tracheostomy, which are also part of the intended patient population of these Trilogy ventilator devices." In other words, the Health Hazard Evaluation was conducted on a population that was not the targeted population. Therefore, the results were skewed positively.

127. According to the FDA, an internal report at Philips, known as Health Hazard Evaluation ER2227646 V06, further documents "the risk and hazard evaluation based on the use of a humidifier and/or bacterial filter with the use of Trilogy 100 and 200 ventilator devices, but neither component nor attachment is required for proper use of these ventilators."

128. In summary, Philips in 2018 – after years of complaints – initiated an informal CAPA that only evaluated Trilogy Devices on an incorrect patient population using addition accessories not required for use of the Trilogy Devices.

129. The FDA further found that CAPA INV 0988, and the related evaluations and studies, were insufficient because they failed to consider known data at that time. In Health Hazard Evaluation ER2227646 V06, Philips reports 17 complaints related to degradation of air inlet path

foam. However, a search of the complaint database from 2008 to 2017 found over 175,000 total complaints with related keywords, of which 20,000 were associated with Trilogy devices.

130. As the FDA later found, CAPA INV 0988 "did not accurately reflect the probability and severity of harm related to such foam degradation" because "potential foam degradation in Trilogy ventilator devices is not an isolated incident, and you also have not documented a detailed rationale for why harm is not likely to occur again."

131. A corrective action was instituted as a result of CAPA INV 0988. According to the FDA's findings, Philips issued a so-called "Field Communication," which required that in certain circumstances the Inlet Air Path Assembly and Removable Air Path Foam in Trilogy devices were to be replaced. This corrective action was not reported to the FDA as required under the relevant regulations. And, according to the FDA, Philips did not even verify whether the procedure was effective.

132. At all relevant times, Philips had a Quality & Regulatory Committee that met periodically to discuss quality and regulatory concerns related to its products. Annual Report for the year ended December 31, 2021 ("2021 20-F") at 107. In 2018, as a result of a Consent Decree entered into with the Justice Department, Philips established a Quality & Regulatory Committee that met in all subsequent relevant years. According to the 2019 20-F: "The Quality and Regulatory Committee was established in view of the importance of the quality of the company's products, systems, services, and software. The Committee provides broad oversight of compliance to the regulatory requirements that govern the development, manufacturing, marketing and servicing of the company's products." One of the things discussed at the meetings were "[c]omplaint handling and post market surveillance." In 2018, "[t]he Chief Executive Officer and the Chief Quality Officer were present during" the seven meetings of the Quality & Regulatory

Committee. Significantly, Defendant Van Houten attended all the Quality & Regulatory Committee meetings held in 2018, 2019, 2020, and 2021. 2021 20-F at 123.[5]

133. However, none of the risks associated with the Foam was disclosed to the public, who kept on using these products not knowing the risk caused by them. For the year ended 2018, sales from the Company's Sleep & Respiratory Care business accounted for 24% of all income from sales in the Personal Health segment. For the same year, the Company reported income from sales from Personal Health of €7,228,000 and Company-wide income from sales of €18,121,000.

134. A test report dated December 12, 2018, found that "[t]here was a problem of degradation of the damping foam in Trilogy Respironics appliance in 2016." FDA Form 483 at 5. As complaints about the devices continued to roll in, a formal CAPA, CAPA 7211, was finally opened on June 19, 2019, according to the FDA. Even then, CAPA 7211 concerned Trilogy ventilators only.

135. According to the FDA, another test report was generated in 2019 related to the already well-documented issues with the Foam. The test report, dated May 22, 2019, concluded that additional polyurethane samples were analyzed for foam degradation and showed a "chemical reaction" occurring when the foam was exposed to high heat and humidity. FDA Form 483 at 5. The report refers to "significant evidence" but the details are redacted. *Id*.

136. According to the FDA, also in May, four CPAP units were returned to a service center with degraded sound abatement foam.

137. In 2019, according to the FDA, Philips was also testing DreamStation 1 emissions. And the DreamStation 1 was failing – releasing toxic levels of Formaldehyde.

[5] In 2019, the CEO, CLO, and Chief Quality Officer were present at the eight meetings of the Quality & Regulatory Committee. In 2020, the CEO, CLO, COO, and Chief Quality & Regulatory Officer were present at the five Quality & Regulatory Committee meetings.

138. As complaints about the Devices continued to roll in, a formal CAPA, CAPA 7211, was finally opened on June 19, 2019, according to the FDA. Even then, CAPA 7211 concerned only Trilogy ventilators.

139. However, Philips remained silent and its sales continued to increase. For the year ended 2019, sales from the Company's Sleep & Respiratory Care business accounted for 47% of all income from sales in the Connected Care segment. For the same year, the Company reported income from sales from Connected Care of €4,674,000 and Company-wide income from sales of €19,482,000.

140. As a result of rising complaints and CAPA 7211, polyester polyurethane foam degradation issues concerning CPAPs, BiPAPs, and Trilogy Ventilators were discussed at all management review meetings, since January 31, 2020, according to the FDA. However, Philips kept promoting and selling its products, stating that its Devices were "quality" products and complied with FDA and ISO requirements and guidance.

141. In 2020, there was more evidence that Philips' products could be toxic. According to the FDA, two different reports dated January 30, 2020 examined 2019 emissions testing of the DreamStation 1. Each report documented "that the tolerable limits of the Formaldehyde compound were exceeded." A January 30, 2020, internal analysis documented that the DreamStation (1) CPAP device failed emissions testing for VOCs and Aldehydes. FDA Form 483 at 6. The related tests were conducted between January 18, 2019, and January 25, 2019, and between January 25, 2019, and February 1, 2019. *Id.*

142. However, not only did Philips keep selling the products containing the Foam that were already on the market, it created new products with the Foam. For example, as previously discussed, in April 2020, Philips introduced the E30 ventilator with an immediate production of

15,000 units/week to supposedly aid in the ventilator shortage caused by the COVID pandemic. Philips had received emergency use authorization for this supposedly life-saving device, while not disclosing to the public or to the FDA the severe risks associated with the Foam.

143. According to the FDA, a Biological Risk Assessment, dated June 2, 2020, was conducted by Philips as a result of field reports regarding degraded Foam in various CPAP and ventilator products. The Biological Risk Assessment found there was "potential for carcinogenicity, mutagenicity, and systemic toxicity, ***the biological and toxicological risks from exposure to degraded PE-PUR foam are of concern and the severity of harm is crucial***."

144. Another biological risk assessment test dated July 2, 2020, found that "[c]ompounds of concern were identified as analytes . . . with potential for carcinogenicity, mutagenicity, and systemic toxicity." FDA Form 483 at 7. The report stated that "the biological and toxicological risks from exposure to degraded PE-PUR foam are of concern and the severity of harm is crucial with respect to both the 30 kg and 70 kg patient populations of the System One medical device." *Id*.

145. According to the FDA, on December 10, 2020, Philips prepared yet another damning Biological Risk Assessment. As later quoted in the FDA Form 483, this Biological Risk Assessment states in no uncertain terms that users are at serious risk:

> The cytotoxicity and positive genotoxicity results observed from degraded PE-PUR foam samples indicate a potential patient risk. Potential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure. Overall, based on an understanding of the toxicological significance of the foam degradants and the results of the ISO 10993 testing to include mutagenic responses in both a bacterial and mammalian system, the degraded PE-PUR foam is not considered biocompatible and presents a significant biological risk to those patient populations who are exposed to degraded PE-PUR foam.

146. None of these Biological Risk Assessments were made public. In fact, in public statement after public statement, Philips stressed "safety" as one of its biggest concerns. For example, in describing the Company's E30 ventilator to investors on April 20, 2020 during an earnings call, van Houten said: "[T]he E30 . . . is an adaptation from a bi-plane ventilator, to which we have changed the software, added sensors, added filters, ***so that it is safe and suitable for critical care***."

147. For the year ended 2020, sales from the Company's Sleep & Respiratory Care business accounted for 49% of all income from sales in the Connected Care segment, meaning over 8% of Company income from sales in 2020 were from sales of the at-issue Devices. 2020 20-F at §6.3.2. For the same year, the Company reported income from sales from Connected Care of €5,564,000 and Company-wide income from sales of €19,535,000.

148. In the first month of 2021, the mounting evidence of harm – evidence known to Philips but not the market – continued to grow. According to the FDA, an internal Philips report dated January 11, 2021, stated plainly:

> Based on an understanding of the toxicological significance of the foam degradants and the results of the biological testing to include mutagenic responses in both a bacterial and mammalian system, ***the degraded PE-PUR foam is not considered biocompatible and presents a significant biological risk to patients exposed to the degraded PE-PUR foam. Potential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure.***

149. Another internal analysis dated January 13, 2021, reporting on tests of the Foam used in "various Sleep and Respiratory Care Products" stated that "the test article is considered to be mutagenic," and that the product "is considered to have a cytotoxic potential," meaning it could be toxic to cells. FDA Form 483 at 9-10. And an internal biological risk assessment report dated January 22, 2021, found that the degraded polyester polyurethane foam "is not considered biocompatible and presents a significant biological risk to those patient populations who are

exposed to" the Foam as it includes "mutagenic responses in both a bacterial and mammalian system." *Id.* at 10.

150. During this time, none of this was disclosed to the market. Philips also did not conduct adequate investigations or take sufficient corrective actions.

151. More recently, on May 2, 2022, the FDA issued to Philips Respironics a Notice of Opportunity for a Hearing pursuant to section 518(b) of the FDCA. The FDA stated that "***the unreasonable risk presented by the recalled devices was not caused by*** a failure to exercise due care in the installation, maintenance, repair, or ***use of the devices related to the use of ozone cleaning agents***." (emphasis added.) The FDA also said that "the risk associated with the devices was not caused by the failure of a person other than Philips to exercise due care in the installation, maintenance, repair, or use of the devices at issue."

152. On May 9, 2022, during an investor call with Barclays, Kimberly Trautman, who worked for 24 years at the FDA and was the FDA's Medical Device International Quality Systems expert stated that the FDA invoked section 518(b) to facilitate refunds, not necessarily repairs. According to Trautman, this implies that (1) the FDA has lost faith in the Company to perform the work they had been promising; (2) the FDA did not feel the tests used by the company met certain standards; (3) the FDA did not feel comfortable with the information and data provided to date. Trautman also explained that the June 14, 2021 recall also involved a combination of the FDA developing its evidence and turning it over to DOJ to undergo their own investigation.

153. On August 16, 2022, the FDA updated its safety communication concerning the breakdown of the Foam in the recalled ventilators. Since April 2021, the FDA has received more than 69,000 MDRs, including 168 reports of death, associated with the Foam breakdown or suspected Foam breakdown. From April 2021 through April 30, 2022, the FDA received more

than 21,000 MDRs, including 124 reports of death, associated with the Foam breakdown or suspected Foam breakdown. From May 1, 2022, through July 31, 2022, the FDA received more than 48,000 MDRs, including 44 reports of death, associated with the Foam breakdown or suspected Foam breakdown. A wide range of injuries has been reported in these MDRs, including cancer, pneumonia, asthma, other respiratory problems, infection, headache, cough, dyspnea (difficulty breathing), dizziness, nodules, and chest pain.

154. Users bringing lawsuits against Philips have alleged they developed multiple types of cancers because of their use of the Devices, including Bladder Cancer, Brain Cancer, Breast Cancer, Emphysema, Kidney Cancer, Leukemia, Liver Cancer, Lung Cancer, Lymphatic Cancer, Multiple Myeloma, Oropharyngeal Cancer, Papillary Carcinoma, Pulmonary Fibrosis, non-Hodgkin lymphoma, Prostate Cancer, Stomach Cancer, and Thyroid Cancer.

155. There are at least 5.5 million affected Devices globally. About half of the Devices are in the United States. As of September 28, 2022, there were 3,660,000 repair kits and replacement devices produced globally. Only 1,840,000 devices were shipped in the U.S.

Materially False and Misleading Statements Issued During the Class Period

156. Throughout the Class Period, Defendants made statements that were materially false and misleading when made because they omitted the following material information necessary to make them not misleading under the circumstances in which they were made. This material information, known to Philips at different times throughout the Class Period, includes, *inter alia*, that: (i) Philips had deficient product manufacturing controls or procedures; (ii) the Company's sales revenues from the Company's BiPAP and CPAP devices were unsustainable because of the substantial risk of regulatory action or product recall; (iii) in 2015, Philips received multiple complaints about foam degradation issues, as evidenced by an October 30, 2015 communication Philips sent to its foam supplier and later by Philips' own internal reports; (iv) on

or around November 15, 2015, Philips was made aware of a preventative maintenance servicing procedure implemented by another Philips entity in another country on Trilogy ventilator products, but did not institute a CAPA as they should have and, in fact, failed to conduct any "further investigation, health hazard evaluation, risk analysis, or design review. . . in response to foam degradation issues and complaints in the field related to Trilogy ventilator products"; (v) a Philips report, dated April 1, 2016, which utilized field samples obtained in October 2015 from a Trilogy device, "document[ed] base polymer cleavage and embrittlement of the returned foam material of the related field samples"; (vi) a Philips test report dated August 30, 2016 focusing on samples from the Trilogy 200 ventilator was conducted as a result of "field reports/complaints regarding foam degradation in Trilogy 200 ventilator devices in 2015" and found the foam showed "bad resistance against high humidity in combination with high temperature"; (vii) a November 25, 2016 Philips test report, again resulting from "field reports/complaints regarding foam degradation in Trilogy 200 ventilator devices in 2015" documented that other tested foams had better resistance to high humidity at high temperature; (viii) Philips received approximately eighty complaints related to foam degradation, on non-Trilogy ventilator Devices, from 2014 to 2017; (ix) Philips' consumer complaints from January 2008 to 2017 resulted in over 175,000 hits for the "keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black"; (x) in April 2018, the Company opened an informal CAPA to examine Trilogy 100 and 200 Devices (but not products with similar design) due to units returning from the field where foam was degrading and getting into the motor/air path, but it was closed two months later and no formal CAPA was ever initiated; (xi) even the reports associated with the informal CAPA were found to be "inadequate because they [did] not accurately reflect the known data at that time"; (xii) in response to the informal CAPA, Philips issued a so-called "Field Communication," which required in certain

circumstance the Inlet Air Path Assembly and Removable Air Path Foam were to be replaced, but no verification of the effectiveness of this procedure was performed, nor was it reported to the FDA; (xiii) it was not until June 19, 2019 that Philips implemented a full-fledged CAPA, which even then only concerned Trilogy Devices, did not include all known complaints and "therefore, was not adequately performed to identify, or detect the severity or magnitude of potential quality issues/concerns" and was not reported to the public until 2021; (xiv) the €250 million reserve taken would be inadequate; (xv) the Company sought to deflect responsibility by blaming ozone cleaning products; (xvi) the silicone-based foam used in the replacement program (and used in a singular, similar device marketed outside the U.S.) failed a safety test because of the release of certain chemicals of concern, called volatile organic compounds (VOCs); and (xvii) because of the aforementioned, and the failure to properly analyze or report any of it, Philips was in violation of FDA and ISO regulation and guidance at all times throughout the Class Period.

157. Defendants knew by at latest 2015 that there were problems with the Foam and they were violating FDA regulations by not initiating a CAPA and/or reporting the problems known to them, but they disclosed none of this to the public.

158. The Class Period begins on February 23, 2016, the day the Company filed its Annual Report on SEC Form 20-F for the year ended December 31, 2015 (the "2015 20-F"). Appended to the 2015 20-F as exhibits were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by the Individual Defendants, attesting that "[t]he [2015 20-F] fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and information contained in the [2015 20-F] fairly presents, in all material respects, the financial condition and results of operations of the Company."

159. In the 2015 20-F, in a section containing a message from van Houten to Philips' shareholders, the 2015 20-F stated, in relevant part:

> In 2015, our multi-year Accelerate! program again helped us to step up growth and increase margins, despite deteriorating macro-economic conditions in a number of markets. Through Accelerate! and the implementation of the Philips Business System (PBS) we continue to drive improvements across the organization. The PBS is helping us to ***further tighten our focus on quality and excellence*** and enhance productivity through continuous improvement methodologies, while embedding new capabilities and making us more agile, entrepreneurial and customer-centric, with a culture of higher performance.

160. In the 2015 20-F, in explaining its Sleep & Respiratory Care business, the Company stated that its "products improve patient outcomes, provide better value, and help secure access to high-quality care, while reducing environmental impact."

161. In the 2015 20-F, in explaining its Healthcare portfolio, which the Sleep & Respiratory Care products were considered part of that year, the Company stated: "Our Accelerate! program continues to drive improvements in healthcare, resulting in enhanced customer centricity and service levels, faster time-to-market for our innovations, strengthened quality and compliance systems, and better cost productivity. We increased our investments in, among others, healthcare informatics, personal health solutions and our quality systems."

162. In the 2015 20-F, the Company further stated:

> At Philips, we deliver innovative, integral technology solutions designed to create value by ***improving the quality*** and delivery of care while lowering cost. Our broad and deep clinical expertise and technology leadership across the health continuum and commitment to customer collaboration are core to our business and truly differentiate us.
>
> Philips is one of the world's leading healthcare companies (based on sales) along with General Electric and Siemens. The competitive landscape in the healthcare industry is evolving with the emergence of a considerable number of new market players. The United States, our largest market, represented 43% of Healthcare's global sales in 2015[.]

163. In the 2015 20-F, the Company also stated:

Commitment to quality

. . . ***We are committed to compliance with*** regulatory product approval and ***quality system requirements*** in every market we serve, ***by addressing specific terms and conditions of*** local and ***national regulatory authorities including the US FDA***[.]

[. . .]

7.5 Compliance risks

[. . .]

Philips is exposed to non-compliance with data privacy and product safety laws.

Philips' brand image and reputation ***would be*** adversely impacted by non-compliance with various product safety laws[.] . . . Philips is exposed to the risk that its products, including components or materials procured from suppliers, ***may*** prove to be not compliant with safety laws, e.g. chemical safety regulations. Such non-compliance could result in a ban on the sale or use of these products.

Philips operates in a highly regulated product safety and quality environment. Philips' products are subject to regulation by various government agencies, including the FDA (US) and comparable foreign agencies. . . . ***The risk exists that product safety incidents or user concerns could trigger FDA business reviews which, if failed, could lead to business interruption which in turn could adversely affect Philips' financial condition and operating results.*** E.g. the voluntary, temporary suspension in 2014 of new production at our Healthcare facility in Cleveland, Ohio targeted to further strengthen manufacturing process controls after certain issues in this area were identified during an ongoing FDA inspection.

164. The Healthcare portfolio increased from 2014. The Company reported EBITA amounted to EUR 1,024 million, or 9.4% of sales, compared to EUR 616 million, or 6.7% of sales, in 2014.

165. The statements referenced in ¶¶ 158-64 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(v), (viii), (ix) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products.

166. On April 25, 2016, the Company announced its earnings for the first quarter of 2016. The Company reported positive sales increase for its HealthTech, including the Sleep & Respiratory Care products. Specifically, in relation to the DreamStation products, the Company

reported the "Dream Family solution, which is designed to provide the sleep therapy experience for people with obstructive sleep apnea, is showing strong traction in Europe and the US, with more than 200,000 Dream Family users since its introduction in 2015[.]" The Company also reported "mid-single-digit growth in Sleep & Respiratory Care."

167. That same day, the Company hosted an earnings call with investors to discuss the Company's financial and earnings results for the First Quarter of 2016 (the "1Q2016 Earnings Call"). During the 1Q2016 Earnings Call, Bhattacharya stated: "I would also like to remind you that in Q1, the profitability of our Sleep & Respiratory Care business within [P]ersonal Health was negatively impacted by about 100 basis points, as anticipated, due to the change in the US reimbursement for home ventilation which we are able to partly offset by a strong performance of the recently introduced Dream Family sleep therapy program. We expect this negative headwind from this change in reimbursement to have a similar impact in Q2." In response to an analyst's questions concerning the "Personal Health margin" for the quarter, Bhattacharya stated: "The first quarter was partially impacted, as we said, with the Sleep & Respiratory business because it had a dip compared to last year with the reimbursement cuts."

168. During the 1Q2016 Earnings Call, van Houten said: "Sleep & Respiratory Care achieved mid-single-digit growth, driven in particular by Philips' new Dream Family sleep therapy program which we launched in Europe and in the United States. This Dream Family helps to improve the sleep therapy experience for people with obstructive sleep apnea. To date, more than 200,000 people are using the Dream Family in the United States since its introduction in the fourth quarter of 2015. We are now launching this in Japan."

169. The statements referenced in ¶¶ 166-68 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(vi), (viii), (ix) and (xvii),

particularly because Philips had already received multiple complaints about the Foam being used in its products and had already documented Foam breakage issues in a report dated April 1, 2016.

170. In the Company's 2015 Annual Report to Shareholders, "Analyst Selection," released on or about May 12, 2016, van Houten said: "Our Health & Wellness and Personal Care businesses performed very well, delivering another year of high growth and margin expansion."

171. On May 12, 2016, at the Annual General Shareholders meeting, van Houten said: "Philips brand is ideally positioned to provide chronic care solutions to people right into their home setting and we aim to expand our portfolio in this decision. For example, for people with a chronic sleep condition, we introduced the Dream Family which delivers sleep therapy for people with obstructive sleep apnea. The range includes sleep masks, but [*sic*] also devices that are connected to the cloud, allowing online coaching of the patient. In just a few months, we have already gained more than 200,000 users!"

172. The statements referenced in ¶¶ 170-71 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(vi), (viii), (ix) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products, had already documented Foam breakage issues in a report dated April 1, 2016, and knew there was a great risk that problems with the Foam would impact the Dream Family line.

173. On July 25, 2016, the Company announced its earnings for the second quarter of 2016. Again, the Company boasted high-single-digit growth in Sleep & Respiratory Care, which drove growth in the Company's Personal Health business.

174. That same day, the Company hosted an earnings call with investors to discuss the Company's financial and earnings results for the Second Quarter of 2016 (the "2Q2016 Earnings Call"). During the 2Q2016 Earnings Call, van Houten said: "One of the strong performers in the

Personal Health segment is our Sleep & Respiratory Care business. This business grew high single-digit, driven by mid-teens growth in sleep as a result of the rollout of the Dream Station portfolio, which is also driving increased customer satisfaction and market share gains."

175. During the 2Q2016 Earnings call, an analyst inquired of the growth outlook for Philips' Personal Health segment. In response, van Houten said: "[W]e are committed to mid to high single-digit growth in Personal Health. We believe that, that is suitable. We see that in multiple of the business groups; for example, Sleep and Respiratory care performed very well, lots of innovation going on there with our cloud-based connected sleep solutions. We are outpacing competition there."

176. The statements referenced in ¶¶ 173-75 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(vi), (viii), (ix) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products, had already documented Foam breakage issues in a report dated April 1, 2016, and knew there was a great risk that problems with the Foam would impact the Dream Family line.

177. On October 24, 2016, the Company announced its earnings for the third quarter of 2016. The Sleep & Respiratory Care division again experienced high-single-digit growth over the quarter. Specifically, the Company represented that its "Personal Health businesses grew by 7% on a comparable basis, with growth across the portfolio." The Company's "adjusted EBITDA" for the Personal Health portfolio was "supported by high-single digit growth in Sleep & Respiratory Care," contributing to an increase "by 130 basis points" in adjusted EBITDA "as a result of higher sales volumes as well as improved cost productivity."

178. That same day, the Company hosted an earnings call with investors to discuss the Company's financial and earnings results for the Third Quarter of 2016 (the "3Q2016 Earnings Call"). During the 3Q2016 Earnings Call, van Houten said:

> We continued our strong momentum in the Personal Health businesses as sales grew by 7% on a comparable basis and adjusted EBITDA improved by 130 basis points as a result of higher sales volumes as well as improved cost productivity.
>
> Sales grew across the entire Personal Health portfolio, most notably double-digit growth in Health & Wellness and supported by high-single digit growth in Sleep & Respiratory Care and mid-single digit growth in Personal Care and Domestic Appliances.
>
> We continue to see strong adoption around the world of our leading Personal Health solutions. Growth geographies in Western Europe grew in the high-single digits, while North America grew mid-single digit. We remain committed to sustaining mid- to high-single digit growth in Personal Health, enabled by our strong innovation pipeline.

179. The statements referenced in ¶¶ 177-78 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(vi), (viii), (ix) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products, had already documented Foam breakage issues in a report dated April 1, 2016, knew there was a great risk problems with the Foam would impact further growth of the Sleep & Respiratory line.

180. On January 24, 2017 (the "January 24, 2017 Release"), the Company released its fourth quarter and full year highlights. In the Company's 2016 Annual Report to Shareholders, van Houten said: "Throughout market-leading propositions in Personal Health, we have natural touchpoints with consumers to promote healthy lifestyles, which are critical to good health. For example, our Dream Family is a comprehensive solution comprising sleep therapy devices, a comfortable masks [*sic*], therapy management software and services to provide a good night's sleep for people with obstructive sleep apnea."

181. The Company further stated: "Building on the success of the integrated Dream Family solution in the US, Europe and Japan, the Philips DreamStation Go portable CPAP solution was introduced. DreamStation Go is a compact and lightweight device designed to provide sleep therapy for travelers with obstructive sleep apnea."

182. The January 24, 2017 Release reported mid-single-digit growth in the Sleep & Respiratory Care division quarter-over-quarter. The Company reported a "19% improve in Adjusted EBITA to EUR 1 billion, net income of EUR 640 million and sales of EUR 7.2 billion in Q4, with the HealthTech portfolio growing at 5%."

183. On January 24, 2017, the Company hosted an earnings call with investors to discuss the Company's financial and earnings results for the Fourth Quarter of 2016 (the "4Q2016 Earnings Call"). During the 4Q2016 earnings Call, van Houten said:

> The Personal Health businesses grew by 7% on a comparable basis[.] . . .
>
> There was growth across the portfolio, led by double-digit growth in Health & Wellness and high-single-digit growth in Domestic Appliances, while the adjusted EBITA margin improved by 100 basis points in the fourth quarter.
>
> For the Personal Health businesses in mature geographies we had comparable sales growth in the high-single-digits, driven by double-digit growth in Western Europe and high-single-digit growth in North America. This was partly offset by a low-single-digit decline in other mature geographies.
>
> [. . .]
>
> We remain committed to sustaining mid- to high-single-digit sales growth in Personal Health, enabled by our strong innovation pipeline.
>
> [. . .]
>
> Building on the success of the Philips' integrated Dream Family solution in the United States, Europe and Japan, we recently introduced a Philips DreamStation Go portable CPAP solution. DreamStation Go is a compact and lightweight device designed to provide sleep therapy for travelers with obstructive sleep apnea.

184. The statements referenced in ¶¶ 180-83 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(ix) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its

products, had already documented Foam breakage issues in a report dated April 1, 2016 and, in another report, dated November 25, 2016, had already documented issues when the Foam was exposed to high humidity or high temperature.

185. On February 21, 2017, the Company filed its Annual Report on SEC Form 20-F for the year ended December 31, 2016 (the "2016 20-F"). Appended to the 2016 20-F as exhibits were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by the Individual Defendants, attesting that "[t]he [2016 20-F] fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and information contained in the [2016 20-F] fairly presents, in all material respects, the financial condition and results of operations of the Company."

186. In the 2016 20-F, in a message from van Houten to shareholders, the Company stated: "[W]e again stepped up our investments in quality, growth initiatives and innovation." Van Houten continued, "With a strong commitment to continuous improvement, we will deliver the meaningful innovation and quality our customers expect—and take the next steps on our journey to reach our goal of improving the lives of 3 billion people a year by 2025!"

187. In the 2016 20-F, the Company stated:

> **Segment performance 3.1.1**
> For [products including the Devices], we are subject to the applicable requirements of the US FDA.
>
> [. . .]
>
> **Commitment to quality**
> . . . ***We are committed to compliance with*** regulatory product approval and ***quality system requirements*** in every market we serve, ***by addressing specific requirements of*** local and national regulatory authorities including ***the US FDA***[.]
>
> [. . .]
>
> **5.5 Compliance risks**
>
> *Philips is exposed to non-compliance with product safety laws and data privacy.*

> . . . Philips is exposed to the risk that its products, including components or materials procured from suppliers, ***may*** prove to be not compliant with safety laws, e.g. chemical safety regulations. Such non-compliance could result in a ban on the sale or use of these products.
>
> Philips operates in a highly regulated product safety and quality environment. Philips' products are subject to regulation by various government agencies, including the FDA (US) and comparable foreign agencies. . . . The risk exists that ***product safety incidents or user concerns could trigger FDA business reviews which, if failed, could lead to business interruption which in turn could adversely affect Philips' financial condition and operating results***.

188. The Company reported sales rose to EUR 17.4 billion in its HealthTech portfolio. On a comparable basis sales increased by 5% in the portfolio, which includes the Sleep & Respiratory Care division. There was a reported mid-single-digit growth in Sleep & Respiratory Care as compared to the previous year.

189. The statements referenced in ¶¶ 185-88 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(ix) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products, had already documented Foam breakage issues in a report dated April 1, 2016 and, in another report, dated November 25, 2016, had already documented issues occurring when the Foam was exposed to high humidity or high temperature.

190. On April 11, 2017, Philips announced the release of yet another product using the same Foam it knew to be dangerous. In a release announcing the new DreamStation Go sleep therapy device, Philips did not warn of any potential issues with Foam degradation. Instead, the Company described the product as "its newest and smallest positive airway pressure (PAP) device designed to simplify travel for patients living with obstructive sleep apnea (OSA)."

191. The Company further stated about the DreamStation Go:

> DreamStation Go delivers the same clinically-proven performance and comfort, for reliable, convenient therapy on-the-go.

> Designed with traveling patient needs in mind, DreamStation Go is the product of over 30 years of sleep therapy innovation.
>
> . . .
>
> OSA affects more than 100 million people worldwide[i], many of whom rely heavily on PAP therapy to improve their quality of life. DreamStation Go is available in either a fixed-pressure continuous positive airway pressure (CPAP) or auto-titrated APAP model. Both options are Bluetooth-enabled for seamless data transmission to Philips' EncoreAnywhere and Care Orchestrator cloud-based patient management systems for clinicians. Integration with Philip's DreamMapper application enables users to easily monitor therapy adherence across multiple devices from one consolidated dashboard.
>
> DreamStation Go is the latest addition to Philips' award-winning Dream Family of sleep apnea products focused on connecting and supporting the patient, clinician, and homecare provider to enhance patient care and quality of life. Dream Family has impacted more than one million patient lives since launched in 2015.

192. The statements referenced in ¶¶ 190-91 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(ix) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products, had already documented Foam breakage issues in a report dated April 1, 2016 and, another report, dated November 25, 2016, had already documented issues when the Foam was exposed to high humidity or high temperature. Therefore, Philips was marketing the DreamStation Go with the Foam knowing – but not revealing – there were risks associated with the Foam.

193. On April 21, 2017, Philips announced results from a recent study, that Philips sponsored, that supposedly showed "significant decreases in both hospital and payer costs and hospitalization rates for severe chronic obstructive pulmonary disease. . . with the use of advanced noninvasive ventilation (NIV), specifically Philips Trilogy 100 with AVAPS-AE mode, compared to no NIV or the use of less advanced NIV therapy following patient discharge."

194. The April 21, 2017 release detailed the growing burden COPD places on healthcare providers and individuals. Philips stated:

> In an effort to lessen this burden, the Philips-sponsored study reviewed how hospitals and payers can more efficiently and effectively manage this COPD treatment and related comorbidities by implementing an advanced mode of NIV in the home care setting. This was reviewed in a multifaceted program that incorporates a combination of therapies including treatment using advanced NIV therapy provided by Philips Trilogy100 (AVAPS-AE modality), oxygen therapy, respiratory therapist-led care, patient education and medication reconciliation. This at-home program has now proven its potential to provide both hospitals and payers with tremendous savings while also offering the patient with treatment at home.
>
> . . .
>
> With COPD being the most common cause for readmissions, this data supports the role of home care in COPD management. Available globally, the Philips Trilogy100 device used in this study offers the unique AVAPS-AE modality designed to tailor treatment and provide increased support for patients from hospital to home, while automating the titration process. It is the most widely dispensed portable ventilator in North America

195. The statements referenced in ¶¶ 193-94 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(ix) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products, had already documented Foam breakage issues in a report dated April 1, 2016 and, another report, dated November 25, 2016, had already documented issues when the Foam was exposed to high humidity or high temperature. Therefore, Philips was promoting the use of the Trilogy100 device as reducing health risks and costs while withholding the truth about the risks associated with the device.

196. On April 24, 2017, the Company released its earnings for the First Quarter of 2017. The release reported that sales increased to EUR 5.7 billion, with comparable sales growth of 3% in the HealthTech portfolio. Sleep & Respiratory Care again recorded high-single-digit growth.

197. On April 24, 2017, the Company hosted an earnings call with investors to discuss the Company's financial and earnings results for the First Quarter of 2017 (the "1Q2017 Earnings Call"). During the 1Q2017 Earnings Call, Bhattacharya said:

> Growth of 5% . . . in Personal Health was driven by high single-digit growth in Health & Wellness and Sleep & Respiratory Care, where we saw another quarter of strong double-digit growth in the patient interface business with continued market share gains.
>
> As Frans mentioned, in Health & Wellness, we have a solid pipeline of new product introductions[.] . . . We will also launch the Philips DreamStation Go portable CPAP solutions. We will back these launches with the requisite support in advertising and promotion, which will have a dampening effect on the results of Personal Health in the second quarter. However, I hasten to add that we do expect to have continued improvements in operating results for Personal Health.

198. During the 1Q2017 Earnings Call, in response to an analyst's question concerning "what kinds of works [*sic*] or progress you've made on actually addressing what the FDA has brought to your attention" concerning issues with regulatory non-compliance, van Houten said:

> The PH [(*i.e.*, Personal Health)] margin is very much driven by strong innovations. Now in the quarter, we saw high single-digit growth in Health & Wellness, high single-digit growth in Sleep & Respiratory care. Both categories are above average in profitability for Personal Health. And therefore, overall, with that growth rate, we also saw a further mix improvement. And that then drove a nice profit expansion that can change a little bit if the mix changes through the year, right? So I'd say from a seasonality point of view, the mix is not equal in every quarter, right, that you need to take into account. But otherwise, ***we are very confident that Personal Health is on a good path and that we continue the improvement***. . . .

199. The statements referenced in ¶¶ 196-98 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(vii), (viii), (ix) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products, had already documented Foam breakage issues in a report dated April 1, 2016 and, another report, dated November 25, 2016, had already documented issues when the Foam was exposed to high humidity or high temperature.

200. On July 24, 2017, the Company released its earnings for the Second Quarter of 2017. The release reported that sales totaled EUR 4.3 billion, with comparable sales growth of 4%. Net income from continuing operations amounted to EUR 161 million, driven by a 15% increase in Adjusted EBITA to EUR 439 million. The Company's Personal Health businesses saw a "6% comparable sales growth" that the Company ascribed to "double-digit growth in Health & Wellness, high-single-digit growth in Personal Care and mid-single-digit growth in Sleep & Respiratory Care."

201. That same day, the Company hosted an earnings call with investors to discuss the Company's financial and earnings results for the Second Quarter of 2017 (the "2Q2017 Earnings Call"). During the 2Q2017 Earnings Call, van Houten announced:

> Within the Personal Health segment of sleeper respiratory [*sic*] care, we signed an agreement to acquire Respirtech, a US based provider of an innovative airway clearance solution for patients with chronic respiratory conditions. Highly complementary products to our existing portfolio will help those patients to receive the care they need at home. Also Respirtech will be accretive to growth and margins as of the first year.

202. During the 2Q2017 Earnings Call, in response to an analyst's questions about the Company's recent mergers and acquisitions, van Houten described the Company's Sleep & Respiratory Care business as "a high-performing business group that is delivering steady mid-single-digit growth and high profitability."

203. The statements referenced in ¶¶ 200-202 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(ix) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products, had already documented Foam breakage issues in a report dated April 1, 2016 and, another report, dated November 25, 2016, had already documented issues when the Foam was exposed to high humidity or high temperature. Philips knew or was reckless in not knowing that

problems with the Foam would impact sales, but the Company did not adequately disclose this risk.

204. On October 23, 2017, the Company released its earnings for the Third Quarter of 2017. The release reported sales of EUR 4.1 billion, with comparable sales growth of 4%, net income from continuing operations increased to EUR 263 million, reflecting a 12% increase in Adjusted EBITA to EUR 532 million. Sleep & Respiratory Care again recorded high-single-digit growth. The Company reported "5% comparable sales growth of the Personal Health businesses," which it ascribed to "high-single-digit growth in Sleep & Respiratory Care." The adjusted EBITA margin improved by 130 basis points for the Sleep & Respiratory Care businesses.

205. On October 23, 2017, the Company hosted an earnings call with investors to discuss the Company's financial and earnings results for the Third Quarter of 2017 (the "3Q2017 Earnings Call"). During the 3Q2017 Earnings Call, van Houten said:

> COPD is the most common cause of hospital readmissions and ***a recent study showed that with Philips' Trilogy home ventilators providers can save millions in readmission cost*** [*sic*]. We have expanded our market-leading home ventilation offering with the launch of the connected Trilogy ventilator in North America, linking it to the Philips' Care Orchestrator. Care Orchestrator is a unique patient management service for people living with chronic respiratory and sleep conditions. This service effectively provides care coordination between patients, homecare workers, doctors, hospitals and payers, all enabled by our HealthSuite digital cloud platform***. The combination of the connected Trilogy ventilator and the CareSage service provides a clinically-validated solution for COPD management which is expected to help providers lower care costs and reduce hospital admissions while improving the patient experience***.

206. During the 3Q2017 Earnings Call, van Houten touted the quality of Philips' products, stating:

> Let me stress that ***there is no concern on product quality***. ***Our products are market-leading, also in the area of quality and reliability and are highly appreciated by our customers.*** Further, as expected, the FDA conducted an inspection of our Cleveland facility in the quarter. In accordance with normal practice, we submitted our response to inspection findings for review by the FDA.

> ***We are committed to delivering high-quality innovative products and solutions and over the last years, we have made significant progress in our quality management regulation compliance***.

207. The statements referenced in ¶¶ 204-206 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(ix) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products, had already documented Foam breakage issues in a report dated April 1, 2016 and, another report, dated November 25, 2016, had already documented issues when the Foam was exposed to high humidity or high temperature. While van Houten stated publicly "there is no concern on product quality," Philips' internal documents paint a different picture.

208. In the 2017 Annual Report to Shareholders, "Analyst Selection," released on or about January 30, 2018, van Houten stated: "We continue to drive quality and regulatory performance improvement throughout the company. Nevertheless, we did not fully deliver to our 2017 plan as we continue to address two significant regulatory challenges that arose from two years ago. We must continue our improvement journey forcefully."

209. In the 2017 Annual Report to Shareholders, released on or about January 30, 2018, the Company stated:

> Philips' Sleep & Respiratory Care business continues to grow in respiratory care, with strong acceptance of its market-leading home ventilation offerings. ***This portfolio was further extended with the launch of the connected Trilogy ventilator in North America***, linking it to Philips' unique patient management solution Care Orchestrator. In sleep care, continued mask share gains were driven by strong traction of the DreamWear family of masks, including the recently introduced DreamWear Pillow mask.
>
> Philips acquired Respiratory Technologies, a US-based provider of an innovative airway clearance solution for patients with chronic respiratory conditions.

210. On January 30, 2018, the Company hosted an earnings call with investors to discuss the Company's financial and earnings results for the Fourth Quarter of 2017 (the "4Q2017 Earnings Call"). During the 4Q2017 Earnings Call, van Houten said:

> *Expansion*
> In the third quarter of 2017, we expanded our market leading home ventilation offering was [*sic*] the launch of the wirelessly connected Trilogy Ventilator in North America linking it to the cloud-based platform Care Orchestartor which is powered by the Philips Healthsuite digital platform. This established a ***clinically validated*** solution COPD management which will help providers' [*sic*] lower care cost, reduce hospital admissions while improving patient experience.
>
> Now with connected respiratory care added to our 2.6 billion nights of sleep experience, Philips is leading connected sleep and respiratory therapies in the home.
>
> *Growth*
> The award-winning Trilogy Ventilator as well as our compact sleep therapy system DreamStation GO launched in the second quarter of last year contributed to a double-digit comparable growth in sleep and respiratory devices for the fourth quarter. Our sleep and diagnostics business also experienced mid-teens growth validating our intent to extend the sleep apnea market worldwide. And in-patient interface, we have exciting launches planned in the first [*sic*] of 2018 addressing the full mask, face mask segment, which is the largest segment of the market.

211. During the 4Q2017 Earnings Call, in response to an analyst's question about the number of products in Philips' Personal Health portfolio, van Houten stated: "So obviously, we like businesses that have recurring revenues attached to them. And several of our businesses do in personal health: sleep and respiratory care where you have services and masks. . . ."

212. The statements referenced in ¶¶ 208-11 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(ix) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products, had already documented Foam breakage issues in a report dated April 1, 2016 and, another report, dated November 25, 2016, had already documented issues when the Foam was exposed to high humidity or high temperature. Indeed, the FDA Form 483 revealed that there were 222,000 complaints, over 175,000 of which occurred between 2008 to 2017 found by

searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black. Therefore, Philips knew or was reckless in not knowing the growth it was touting was not sustainable.

213. On February 28, 2018, the Company filed its Annual Report on SEC Form 20-F for the year ended December 31, 2017 (the "2017 20-F"). Appended to the 2017 20-F as exhibits were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by the Individual Defendants, attesting that "[t]he [2017 20-F] fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and information contained in the [2017 20-F] fairly presents, in all material respects, the financial condition and results of operations of the Company."

214. In the 2017 20-F, the Company stated:

> **3.5 Our commitment to Quality**
>
> We continue to drive quality and regulatory performance improvement throughout the Philips Group. Under our governance model, the Executive Committee is ultimately accountable for Quality at Philips, supported by the Quality & Regulatory team. The Quality & Regulatory team drives to one common set of standards through the Philips Quality Management System (PQMS), as well as providing transparency on performance and opportunities for further improvement. Inclusion of quality metrics in monthly business reviews has driven transparency and improvement execution.
>
> . . .
>
> Looking ahead we will continue to raise the performance bar, also including Quality in the evaluation of all senior management. With consistency of purpose, top-down accountability, standardization, and leveraging continuous improvement we aim to drive greater speed in the adoption of a Quality mindset throughout the enterprise.
>
> [. . .]
>
> **4.1.1 About Personal Health businesses**
>
> . . .
>
> Philips' Personal Health businesses are subject to regulatory requirements in the markets where they operate. . . . We have a growing portfolio of medically regulated products in our Health & Wellness, Personal Care and Sleep & Respiratory Care businesses. For these products we are subject to the applicable requirements of the US FDA[.]

[. . .]

> **6.5 Compliance risks**
> Philips operates in a highly regulated product safety and quality environment. Philips' products are subject to regulation (e.g. the new EU Medical Devices Regulation) by various government agencies, including the FDA (US) and comparable foreign agencies. . . . The risk exists that product safety incidents or user concerns could trigger FDA business reviews which, if failed, could lead to business interruption which in turn could adversely affect Philips' financial condition and operating results.

215. In the 2017 20 F, the Company further stated: "Philips' Sleep & Respiratory Care business continues to grow in respiratory care, ***with strong acceptance of its market leading home ventilation offerings***. This portfolio was further extended with the launch of the connected Trilogy ventilator in North America, linking it to Philips' unique patient management solution Care Orchestrator. In sleep care, continued mask share gains were driven by strong traction of the DreamWear family of masks, including the recently introduced DreamWear Pillow mask."

216. The statements referenced in ¶¶ 213-15 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(ix) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products, had already documented Foam breakage issues in a report dated April 1, 2016 and, another report, dated November 25, 2016, had already documented issues when the Foam was exposed to high humidity or high temperature. Indeed, the FDA Form 483 revealed that there were 222,000 complaints, over 175,000 of which occurred between 2008 to 2017 found by searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black. Therefore, Philips knew or was reckless in not knowing the growth it was touting was not sustainable.

217. On April 23, 2018, the Company released its earnings for the First Quarter of 2018. The release reported sales of EUR 3.9 billion, with comparable sales growth of 5%, net income

from continuing operations of EUR 94 million, and the Company's Adjusted EBITA margin increased 130 basis points to 8.7%. Sleep & Respiratory Care again recorded high-single-digit growth. Comparable sales growth in the Company's Sleep & Respiratory Care businesses was "4%, reflecting high-single-digit growth in Sleep & Respiratory Care." "Overall, the Adjusted EBITA margin increased by 30 basis points" across the Personal Health businesses.

218. That same day, the Company hosted an earnings call with investors to discuss the Company's financial and earnings results for the First Quarter of 2018 (the "1Q2018 Earnings Call"). In the 1Q2018 Earnings Call, Bhattacharya stated:

> The Personal Health businesses delivered 4% comparable sales growth, driven by high single-digit growth in Sleep & Respiratory Care. As Frans mentioned, this includes a negative impact of 150 basis points ***due to lower sales in our air purification business in China***.

219. During the 1Q2018 Earnings Call, van Houten said:

> The Personal Health business grew 4% a lower growth compared to previous quarters, due to lower demand in the air purification market in China. This was due to an improvement in the weather conditions in China and government policies to improve air quality. Nevertheless, our portfolio continued to do well as we gained market share in this category. This impacted the comparable sales growth of Personal Health business by approximately 150 basis points.

220. During the 1Q2018 Earnings Call, van Houten also said:

> In Sleep & Respiratory Care, high single-digit comparable sales growth was driven by double-digit growth in the patient interface or masks. In this area, ***we further expanded our integrated Dream Family solutions with the introduction of the DreamWear Full Face mask as part of our award-winning DreamWear platform. With this, we are addressing the largest mask segment. In Respiratory Care, we continued with strong performance led in ventilation by the award-winning Trilogy range.***
>
> Sleep apnea has a high-incident rate globally, yet there is low awareness among the impacted population. To unlock the large value creation potential for Philips, we opened Southeast Asia's first Sleep and Respiratory Education Center in Singapore to train health care professionals from across the region to better diagnose and treat sleep and respiratory disorders.

221. The statements referenced in ¶¶ 217-20 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(x) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products and had already initiated an informal CAPA because of the complaints. Indeed, the FDA Form 483 revealed that there were 222,000 complaints, over 175,000 of which occurred between 2008 to 2017 found by searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black.

222. On July 23, 2018, the Company released its earnings for the Second Quarter of 2018. The release reported sales of EUR 4.3 billion, with comparable sales growth of 4, net income from continuing operations of EUR 186 million, and that the Adjusted EBITA margin increased 100 basis points to 11.2%. Sleep & Respiratory Care again recorded high-single-digit growth. "In the Personal Health businesses, comparable sales growth was 2%, with high-single-digit growth in Sleep & Respiratory Care." "The Adjusted EBITA margin" for the Personal Health businesses "increased by 80 basis points, driven by operational improvements."

223. On July 23, 2018, the Company hosted an earnings call with investors to discuss the Company's financial and earnings results for the Second Quarter of 2018 (the "2Q2018 Earnings Call").

224. During the 2Q2018 Earnings Call, van Houten said:

> The Personal Health businesses grew 2% with high single-digit growth in Sleep & Respiratory Care and low single-digit growth in Personal Care. Growth of the Personal Health businesses was impacted by a high single-digit decline in China, mainly due to an inventory alignment at our online distributors and lower demand in the air purification market. After a slow start, the Personal Health businesses gained momentum in the quarter, and we expect this to continue in the second half of the year. The increase in margin was mainly driven by growth, our productivity program and operational improvements, contributing to an adjusted EBITA margin increase of 100 basis points.
>
> [. . .]

> Following the successful launch of the DreamWear Full Face mask in the United States at the end of the first quarter, the rollout of this new mask in other markets resulted in double-digit growth for Philips in this largest mask segment. Moreover, to further drive growth in the emerging sleep therapy market in China, Philips launched the connected Dream Family solution there.

225. During the 2Q2018 Earnings Call, an analyst inquired of the "single biggest risk to [Philips'] ability" to meet its earnings expectations in the Personal Health business; van Houten responded that "Sleep & Respiratory Care all along has demonstrated high growth as well."

226. The statements referenced in ¶¶ 222-25 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(xii) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products, had already initiated an informal CAPA because of the complaints and even issued an internal corrective procedure (without notification to the FDA). Indeed, the FDA Form 483 revealed that there were 222,000 complaints, over 175,000 of which occurred between 2008 to 2017 found by searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black. Therefore, the growth of this line was unsustainable.

227. On September 21, 2018, in connection with the launch of Trilogy Evo ventilators, John Frank stated:

> Worldwide, chronic conditions are on the rise, presenting continually growing care challenges. Time and again, we have seen the positive impact that connected care can have not only on patients, but on the care teams that serve them. With effective treatment options, chronic respiratory conditions can be managed effectively. Trilogy Evo is our next evolution of work in connected care solutions, making therapy management for chronic conditions easier and more efficient.

228. The statements referenced in ¶ 227 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(vii) and (ix)-(xvii), particularly because Philips had already received multiple complaints about the Foam being used

in its products, and while it was touting its "positive impact" the Company failed to disclose the problems related to the Devices, including the Trilogy Evo. Indeed, the FDA Form 483 revealed that there were 222,000 complaints, over 175,000 of which occurred between 2008 to 2017 found by searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black.

229. On September 28, 2018, van Houten spoke to a packed audience at the University of Amsterdam about Philips' so-called innovations.[6] He stated: "Our purpose is to improve the health of 3 billion people by 2025. Today we are already at 2.1 billion every year that are touched by our products and services. I mentioned that our share price from a low of around EUR 13 in 2012 is currently around EUR 37 and still going up and we have buy ratings from all analysts. So we are on a good path and this journey of change never stops."

230. The statements referenced in ¶ 229 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(xii) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products, Philips was hiding these issues from the public, contradicting van Houten's message that the Company's purpose was to "improve the health of 3 billion people," and the Company's growth in this division was unsustainable. Indeed, the FDA Form 483 revealed that there were 222,000 complaints, over 175,000 of which occurred between 2008 to 2017 found by searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black.

231. On October 22, 2018, the Company released its earnings for the Third Quarter of 2018. The release reported sales of EUR 4.3 billion, with 4% comparable sales growth, that net

[6] A recording of the talk is *available at* https://www.youtube.com/watch?v=SHy9114eDKo.

income from continuing operations increased 17% to EUR 307 million, and Adjusted EBITA margin increased 40 basis points to 13.2%. "In the Personal Health businesses, comparable sales growth was 4%, with mid-single-digit growth in Sleep & Respiratory Care." "The adjusted EBITA margin increased by 10 basis points" for the Personal Care businesses, "reflecting operational improvements, largely offset by adverse currency effects and higher advertising & promotion spend."

232. On October 22, 2018, the Company hosted an earnings call with investors to discuss the Company's financial and earnings results for the Third Quarter of 2018 (the "3Q2018 Earnings Call"). During the 3Q2018 Earnings Call, Bhattacharya attributed a slowdown in Personal Health to "currency headwinds, mainly in Turkey and Argentina, trade sanctions in Iran and supply chain disruptions due to adverse weather conditions like floods in Hong Kong and India."

233. During the 3Q2018 Earnings Call, van Houten said:

> [O]ur Sleep & Respiratory Care business continues to garner attraction for its market-leading home ventilation offering such as the new Trilogy Evo ventilator platform, which is the only portable life-support solution designed to stay with patients as they change care environments.
>
> [. . .]
>
> Sales and cost synergies are on track, and we continue to expect to reach double-digit profitability in the fourth quarter this year

234. During the 3Q2018 Earnings Call, in response to an analyst's questions concerning "long-term headwinds," van Houten said:

> [W]e have 3 high-margin business lines in PH [(*i.e.*, Personal Health)] that are all fantastic. And I would not take the headwinds as structural. We continue to expect strong growth potential in all 3. I mean, I'm referring to Sleep & Respiratory Care, Health & Wellness and Personal Care as businesses with very strong profit potential and growth potential. The guidance that we have given is very much intact on profitability, and we will come back on that during the Capital Markets Day in 2 weeks. We have seen already a step-up in growth from second quarter to third quarter. Abhijit [Bhattacharya] said that we—besides the headwinds on currency, we also have invested about 80 basis points more in advertising and promotion. That's also anticipating a strong fourth quarter.

235. During the 3Q2018 Earnings Call, in response to an analyst's question about the apparent slowdown in momentum in the Company's Personal Health portfolio, van Houten said:

> [T]he Sleep & Respiratory franchise is strong. International markets continue to grow double-digit. In the United States, we have seen a little bit more lumpiness to—in relation to large customer orders. I would say there is nothing structural to be concerned about. The franchise is intact, and we expect also next year a strong growth. Perhaps on the back of this question, happy to report that our endeavors to step-up mask sales is [*sic*] going well. This, of course, always the difference between our competitor and us is that they have more mask sales and we had more systems sales. Therefore extremely pleasing that we are growing double-digit in—on the mask side with our Dream Series masks. And yes, as I said, I see no reason to change our outlook on the Sleep & Respiratory Care business.

236. The statements referenced in ¶¶ 231-35 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(xii) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products, Philips was hiding these issues from the public, contradicting van Houten's message that the Company's purpose was to "improve the health of 3 billion people," and the Company's growth in this division was unsustainable. Indeed, the FDA Form 483 revealed that there were 222,000 complaints, over 175,000 of which occurred between 2008 to 2017 found by searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black.

237. In the 2018 Annual Report to Shareholders, released on or about January 29, 2019, the Company stated:

> The company's wide portfolio of connected consumer health platforms—such as our Sonicare dental solutions and our Dream Family sleep care solution—leverages Philips HealthSuite, a cloud-enabled connected health ecosystem of devices, apps and digital tools that enable personalized health and continuous care.

> . . . In Sleep & Respiratory Care, revenue is generated both through product sales and through rental models whereby revenue is generated over time.[7]

238. In the 2018 Annual Report to Shareholders, released on or about January 29, 2019, the Company stated:

> ***Philips' Sleep & Respiratory Care business continues to gain traction for its market-leading home ventilation offerings, such as the new Trilogy Evo ventilator platform, which is the only portable life support solution designed to stay with patients as they change care environments.*** Integrated with Care Orchestrator, Philips' sleep and respiratory care cloud-based management system, ***Trilogy Evo will help to ease the burden of managing chronic conditions such as Chronic Obstructive Pulmonary Disease (COPD) by allowing physicians, clinicians and care providers to collaborate and coordinate care from hospitals to home by storing their patient prescription and therapy information in a single secure location***.
>
> Philips acquired NightBalance, a digital health scale-up company based in the Netherlands that has developed an innovative, easy-to-use device to treat positional obstructive sleep apnea and positional snoring.
>
> At the consumer electronics show CES 2018, Philips introduced SmartSleep, the world's first and only clinically proven wearable solution for consumers to improve deep sleep quality for people who do not get enough sleep. SmartSleep joins Philips' growing portfolio of smart digital platforms and intelligent solutions that give consumers data-driven insights into their health and access to professional expertise and advise.
>
> ***Highlighting the success of Philips' patient-centric product designs in sleep care, Philips has sold more than 10 million DreamWear CPAP masks and cushions in just three years after the Dream Family platform introduction, growing the DreamWear patient interface sales faster than the market.***

239. On January 29, 2019, the Company released its earnings for the Fourth Quarter of 2018. The release reported that sales increased to EUR 5.6 billion, with comparable sales growth of 5%, income from continuing operations increased to EUR 723 million and Adjusted EBITA margin increased to 17.4%. Sleep & Respiratory Care again recorded high-single-digit growth. "The Personal Health businesses delivered comparable sales growth of 3% in Q4 2018, driven by high-single-digit growth in Sleep & Respiratory Care." "For the full year [(*i.e.*, 2018)], the

[7] 2018 Annual Report at 15.

Personal Health businesses delivered 3% comparable sales growth and an increase in Adjusted EBITA margin to 16.8%."

240. On January 29, 2019, the Company hosted an earnings call with investors to discuss the Company's financial and earnings results for the Fourth Quarter of 2018 (the "4Q2018 Earnings Call"). During the 4Q2018 Earnings Call, Bhattacharya stated: "Sleep & Respiratory Care business continued its strong performance with high single-digit growth for the quarter and the year. The successful launch of the DreamWear Full Face mask at the end of the first quarter continued its good momentum as the fourth quarter and full year delivered double-digit growth for masks overall."

241. During the 4Q2018 Earnings Call, van Houten said:

> Our Sleep & Respiratory Care business continue to perform strongly. We have sold more than 10 million DreamWear CPAP masks and cushions in just 3 years after its introduction, highlighting the success of our patient-centric product design approach in health care. DreamWear is the first and only sleep apnea therapy platform with a modular mask system accommodating cushions to fit 95% of the patient population with nasal, full face and pillow options. With the hose placed on top of the head, the innovative design prevents red marks, discomfort and irritation to the nose bridge for the patient. We are committed to improve the lives of patients living with sleep apnea by developing solutions that enhance the patient experience and comfort.

242. During the 4Q2018 Earnings Call, van Houten said:

> To further align our business with customer needs, we recently announced that we have realigned our internal business structures. Effective as of January 1, 2019 this will lead to changes in the composition of our reporting segments. The most notable changes are the shift to Sleep & Respiratory Care business from the Personal Health segment to the renamed Connected Care segment. The Connected Care businesses focus on patient care solutions, advanced analytics and patient and workflow optimization, both inside and outside the hospital. And aim to unlock synergies from integrating and optimizing patient care pathways leveraging provider-payer-patient business models to positively impact population health and value-based health care.

243. During the 4Q2018 Earnings Call, van Houten said:

> The Personal Health businesses will focus on healthy living and primary preventative care. As a result of moving the higher growth Sleep & Respiratory Care business to the Connected Care segment, we changed the 2019, 2020 growth guidance of both segments. The Connected Care and Personal Health segments' comparable sales growth for 2019-2020 is now expected to be 4% to 6%. And the adjusted EBITA margin is expected to be in the 16% to 18% range by 2020 for each of these segments. There is no change in the 2019 to 2020 sales growth of 5% to 7% nor the 14% to 16% adjusted EBITA margin by 2020 guidance for the Diagnosis & Treatment businesses. And there's also no change to any of the overall Philips Group targets.

244. During the 4Q2018 Earnings Call, in response to an analyst's inquiry about the reorganization of reporting segments affecting Sleep & Respiratory Care, van Houten said:

> [T]he high-growth of Sleep & Respiratory Care will move into Connected Care. And that's the main reason why we adjusted the growth bandwidth for Personal Health to the 4% to 6%. But we have definitely confidence that we can achieve -- that we can be well into that range. And then on the EBITA outlook, as Abhijit promised, we will do a full restate in the course of the quarter so that it will help your own analysis. But there is definitely space for margin expansion. And partly because in 2018, we saw actually some of the high-margin category grow slower due to the supply constraints. Take for example oral care. And in fact, we saw higher growth in some of the Domestic Appliances category. So as the high margin categories come back fully on steam which they should and they will, then we already get a nice mix effect there. Moreover, the productivity program that we have across the company apply to Personal Health as well. We did already referred to the nation's program around marketing transformation, which very much will benefit PH, Personal Health. As we are working on shifting into low marketing spend to outside external working marketing spend which could have significant impact in the -- in how many consumers see our promotions and advertising. So anyway, multiple, as this say in Dutch, (foreign language) in the fire, abilities to improve. And therefore, we remain confident about P[ersonal] H[ealth].

245. During the 4Q2018 Earnings Call, in response to another analyst's inquiry about the reorganization of reporting segments affecting Sleep & Respiratory Care, van Houten stated:

> [T]he guidance change is purely related to the taking out of the high-growth and high profitable Sleep & Respiratory Care business. And there's no change in the underlying expectations that you have on us but that I have on the business. So we actually are on the same side there.

246. During the 4Q2018 Earnings Call, in response to an analyst's inquiry about whether Philips was gaining momentum in the Sleep & Respiratory market space, van Houten stated:

> ***Sleep & Respiratory Care has actually a very strong performance*** in [the] rest of the world. We believe we have gained some share. On the other hand, earlier in the year, (inaudible) did a little bit better than us, so there was also every reason to put the foot on the gas. Overall, I have high confidence in the sustainability of growth for this category. ***There are many people that are not diagnosed with sleep apnea. We are expanding the sleep labs and the collaboration with sleep centers to help aid the Diagnosis & Treatment of all these elements or diseases***. And then moreover, as you remember, ***we have expanded the portfolio from sleep apnea also to sleep disorders*** with the sleep band and so on. And also ***the ability to nudge people when they have light apnea and they don't want to have a full mask solution so with the new products that will further enhance revenue***. And then on the respiratory side, we saw actually -- we are gaining momentum both with the portable oxygen generator as well as the respiratory side. So overall, a positive and optimistic outlook.

247. The statements referenced in ¶¶ 237-46 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(xii) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products, and therefore knew there was a significant risk that performance of the Sleep & Respiratory line could not continue. Indeed, the FDA Form 483 revealed that there were 222,000 complaints, over 175,000 of which occurred between 2008 to 2017 found by searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black.

248. On February 27, 2019, the Company filed its Annual Report on SEC Form 20-F for the year ended December 31, 2018 (the "2018 20-F"). Appended to the 2018 20-F as exhibits were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by the Individual Defendants, attesting that "[t]he [2018 20-F] fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and information contained in the [2018 20-F] fairly presents, in all material respects, the financial condition and results of operations of the Company."

249. In the 2018 20-F, the Company stated:

Our commitment to Quality, Regulatory Compliance and Integrity
Our business success depends on the quality of our products, services and solutions and compliance with many regulations and standards.

. . .

Philips actively maintains FDA/ISO Quality Systems globally that establish standards for its product design, manufacturing, and distribution processes. Our businesses are subject to compliance with regulatory product approval and quality system requirements in every market we serve, and to specific requirements of local and national regulatory authorities including the US FDA[.] . . . We have a growing portfolio of medically regulated products in our Health & Wellness, Personal Care and Sleep & Respiratory Care businesses.

. . .

Failing to comply with the regulatory requirements can have severe legal consequences.

[. . .]

Compliance risks
Philips is exposed to non-compliance with product safety laws, good manufacturing practices and data privacy.

Philips' brand image and reputation would be adversely impacted by non-compliance with various product safety laws, good manufacturing practices and data protection. . . .

. . .

Philips operates in a highly regulated product safety and quality environment. Philips' products are subject to regulation . . . by various government agencies, including the FDA (US) and comparable foreign agencies[.] . . . The risk exists that ***product safety incidents or user concerns***, as in the past, ***could trigger FDA*** business reviews which, if failed, ***could*** lead to business interruption, which in turn ***could*** adversely affect Philips' financial condition and operating results.

250. In the 2018 20-F, the Company further stated: "Our personal Health businesses (as per the 2018 reporting structure) play an important role on the health continuum—in the health living, prevention and home care stages—delivering integrated, connected and personalized solutions that support healthier lifestyles and those living with chronic disease."

251. In the 2018 20-F, the Company further stated: "Leveraging our deep consumer expertise and extensive healthcare know-how, ***we enable people to live a healthy life in a healthy home environment, and to proactively manage their own health***."

252. In the 2018 20-F, the Company stated: "Philips' Sleep & Respiratory Care business continues to gain traction for its market-leading home ventilation offerings, such as the new Trilogy Evo ventilator platform, which is ***the only portable life support solution designed to stay with patients as they change care environments***. . . . Trilogy Evo will help to ease the burden of managing chronic conditions such as Chronic Obstructive Pulmonary Disease (COPD) by allowing physicians, clinicians, and care providers to collaborate and coordinate care from hospital to home[.]"

253. In the 2018 20-F, in reporting on the Personal Health businesses, the Company stated: "In 2018, sales amounted to EUR 7,228 million, a nominal decrease of 1% compared to 2017. Excluding a 4% negative currency effect and consolidation impact, comparable sales were 3% higher year-on-year, reflecting high-single-digit growth in Sleep & Respiratory Care."

254. The statements referenced in ¶¶ 248-53 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(xii) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products, and while it was touting its ability to "enable people to live a health life in a healthy home environment" the Company knew or was reckless in not knowing the harm its products were causing. Indeed, the FDA Form 483 revealed that there were 222,000 complaints, over 175,000 of which occurred between 2008 to 2017 found by searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black.

255. On April 29, 2019, the Company released its earnings for the First Quarter of 2019. The release reported sales of EUR 4.2 billion, with comparable sales growth of 2%, that income from continuing operations increased to EUR 171 million, and that the Adjusted EBITA margin improved to 8.8%. Sleep & Respiratory Care recorded low-single-digit growth. "Comparable sales

in the Connected Care[8] decreased 1%, with low-single-digit growth in Sleep & respiratory Care." "The Adjusted EBITA margin" for the Connected Care businesses "decreased to 8.3%."

256. On April 29, 2019, the Company hosted an earnings call with investors (the "1Q2019 Earnings Call"). During the 1Q2019 Earnings Call, Bhattacharya stated:

> [T]he Sleep & Respiratory business has shown low single digit growth impacted by a decline within our hospital respiratory business.
>
> The successful DreamWear Full Mask range continued its strong momentum delivering double-digit growth for masks overall. The launch of our DreamWisp mask in the first quarter will be supporting growth in the coming quarters as well. . . .

257. During the 1Q2019 Earnings Call, van Houten stated:

> [T]he focus [of the Connected Care business] is on patient care solutions, advanced analytics and patient and workflow optimization inside and outside the hospital and aim to unlock synergies from integrating and optimizing patient care pathways and leveraging provider-payer-patient business models. . . . We've also teamed up with the United States insurance company, Humana, to improve care for at-risk, high-cost populations. . . .
>
> Our therapy solutions to treat obstructive sleep apnea, a condition that affects more than 100 million patients globally, continues to garner healthy demand, supported by the strong reception of the DreamStation GO expanded portable therapy options.

258. The statements referenced in ¶¶ 255-57 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(xii) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products and while it was touting its focus on "patient care solutions" it was not telling the public about the risks patients were facing because of the Company's Devices. Indeed, the FDA Form 483 revealed that there were 222,000 complaints, over 175,000 of which occurred between 2008 to 2017 found by searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black.

[8] Beginning in 2019, the Company reported the results from its Sleep & Respiratory Care line within its Connected Care portfolio.

259. On July 22, 2019, the Company released its earnings for the Second Quarter of 2017. The release reported that sales increased to EUR 4.7 billion, with comparable sales growth of 6% and 8% comparable order intake growth, income from continuing operations increased to EUR 260 million, and Adjusted EBITA improved to 11.8%. Sleep & Respiratory Care again recorded high-single-digit growth. "Comparable sales in the Connected Care businesses increased 6%, with mid-single-digit growth in Monitoring & Analytics and Sleep & Respiratory Care. Comparable order intake showed a mid-single-digit decline, reflecting the uneven order intake dynamics. The Adjusted EBITA margin decreased to 12.1%, mainly due to tariffs, adverse currency impact and mix." The Company reported sales of EUR 1,161 from the Connected Care businesses for the quarter. The Company stated that "Philips' solutions to treat obstructive sleep apnea, a condition that affects more than 100 million patients globally, continue to garner health demand, supported by the continued strong reception for DreamStation GO's expanded portable therapy options."

260. On July 22, 2019, the Company hosted an earnings call with investors to discuss the Company's earnings and financial results for the Second Quarter of 2019 (the "2Q2019 Earnings Call"). During the 2Q2019 Earnings Call, Bhattacharya attributed growth in the Sleep & Respiratory Care business to "the success of the DreamWear Full Face mask and the launch of our DreamWisp minimal contact mask in the first quarter."

261. The statements referenced in ¶¶ 255-60 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(xiii) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products and had finally enacted a formal CAPA to try to investigate the multiple complaints, all of which were being hidden from the investing public. Indeed, the FDA Form 483 revealed that

there were 222,000 complaints, over 175,000 of which occurred between 2008 to 2017 found by searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black.

262. On July 2019, in the interview touting Philips' innovations in the area of CPAP devices- for sleep apnea and portable oxygen concentrators, John Frank stated: "***It's in our DNA. It's what we do quite well***, and our belief is innovation happens only when you stay deeply connected to your core values, and that is staying very close to the markets that you serve." "***It's easy to say, often difficult to do. But our success is based on having very deep, deep insights*** - following the patient's journey, following the pain points that they go through."

263. The statements referenced in ¶ 262 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products, had already documented Foam breakage issues in a report dated April 1, 2016 and, in another report, dated November 25, 2016, had already documented issues when the Foam was exposed to high humidity or high temperature.

264. On October 28, 2019, the Company released its earnings for the Third Quarter of 2019. The release reported sales of EUR 4.7 billion, with comparable sales growth of 6%, EUR 211 million in income from continuing operations, and an adjusted EBITA margin of 12.4%. Sleep & Respiratory Care again recorded mid-single-digit growth. "Comparable sales in the Connected Care businesses increased 5%, with mid-single-digit growth in Monitoring & Analytics and Sleep & Respiratory Care. Comparable order intake was in line with Q3 2018. The adjusted EBITA margin decreased 4.5 percentage points to 11.3%." The Company reported sales of EUR 1,145 from the Connected Care business for the quarter.

265. On October 28, 2019, the Company hosted an earnings call with investors to discuss the Company's earnings and financial results for the Third Quarter of 2019 (the "3Q2019 Earnings Call"). During the 3Q2019 Earnings Call, Bhattacharya stated: "The Sleep & Respiratory Care business grew mid-single digit, partly offset by a decline in home ventilation."

266. During the 3Q2019 Earnings Call, van Houten said:

> Connected Care consists of strong businesses with good profit pools and leading market positions, notably in the attractive franchises of Patient Monitoring & Analytics and Sleep & Respiratory Care. ***These leading businesses represent almost 90% of the Connected Care revenue***. In the near term, the impact of headwinds and several transformations underway, together with the investments to drive future growth in adjacent markets, affect profitability.
>
> The fundamentals of the Connected Care business, however, remain very strong. I'm confident that this segment will contribute to Philips' overall performance improvement. We have made several interventions in the Connected Care businesses during 2019, and we expect that they will start gradually contributing to performance improvement in the coming quarters.

267. During the 3Q2019 Earnings Call, in response to an analyst's questions about what efforts Philips was "taking to improve the operation performance" of the "Connected Care" business, van Houten said:

> Yes, in Connected Care, we have several measures to improve. Now let's first unpack a little bit the various drivers that set us back. So we spoke about the ***headwinds of tariffs***. But besides that, we also saw some more ***price erosion*** in the quarter, which we relate to the need for stricter price management. ***We don't relate it to structural market trends***. And we also saw an ***unfavorable product mix*** in Sleep & Respiratory care basically due to the respiratory side of the house. And we think we can improve the mix going forward in the fourth quarter, therefore, having the benefit of a higher-margin product mix. We also saw some cost elements in the quarter that we do not think will continue and thereby expecting an improvement of profitability coming through quickly. And then finally, you know how we are keen to reduce inventories. And I think we had underestimated a little bit that the effort to reduce inventories would lead to an under-recovery of factory overhead costs. So that also hit us.
>
> Now personally, I don't like it when I need to give you such a long list of stuff because we as management are accountable for that. Now ***we have sat down with the management of Connected Care***, ***even personally I did that again last week***. We feel confident about the measures that are underway. We will expect to see already an improvement in the fourth quarter. Then—and we expect further

> improvement coming through next year. Nevertheless, we felt it was appropriate . . . that we take the guidance of Connected Care somewhat down, recognizing that it will take longer before . . . the adjacencies and the investments in adjacencies will materialize and thereby lifting up the profitability structurally longer term.

268. During the 3Q2019 Earnings Call, in response to an analyst's questions about the Company's Sleep & Respirator Care margins for the quarter, Bhattacharya stated:

> First, let me put the discussion on Sleep [& Respiratory Care] to bed, so to say. So Sleep [& Respiratory Care] is a good business for us, good double-digit growth with very good margin. So that's not the issue. We had good growth in the mass business. We good growth [*sic*] in the system. So that has gone very well. What has happened in Respiratory Care is we have our Home Ventilation business which has very, very high margins actually, which had after many quarters had a decline. Normally, this business was growing double digits. And this happened because of a change in reimbursement qualification criteria, which came into effect in July, where those who claim reimbursement have to undergo further tests, have to show better compliance. So it has increased the paperwork and therefore, in the short term, has caused the decline. This was compensated by stationary oxygen, which has lower margin. So that is what has had an impact on the mix.
>
> [. . .]
>
> [W]e don't, of course, for competitive reasons, don't give margins on all our businesses and a specific guidance on each and every component. But let me just give you a coloring of Connected Care in total. So Monitoring & Analytics and Sleep & Respiratory Care constitute just short of 90%, as Frans mentioned in his speech, right? So these are 2 strong businesses which are—which have very good margins, accretive to the group.

269. The statements referenced in ¶¶ 264-68 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(xiii) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products and had finally enacted a formal CAPA to try to investigate the multiple complaints, all of which were being hidden from the investing public. Indeed, the FDA Form 483 revealed that there were 222,000 complaints, over 175,000 of which occurred between 2008 to 2017 found by searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black.

270. On March 13, 2019, Philips issued a press release discussing a study, sponsored by Philips, entitled *Comparison of Physiological Performance of Four Adaptive Servo Ventilation Devices in Patients with Complex Sleep Apnea* in the American Journal of Respiratory and Critical Care Medicine. The study compared different sleep apnea devices, including the DreamStation ASV. In the release, Philips' Chief Medical liaison, Teofilo Lee-Chiong, stated: "Philips provides healthcare professionals and patients with innovative treatment solutions and services. ***The safety of patients who use our devices is our top priority.*** We also wish to maximize the benefits that patients receive from using our technology."

271. The statements referenced in ¶ 270 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(xiii) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products, which were being hidden from the public, therefore showing that the "safety of patients" was not the "top priority" of Philips. Indeed, the FDA Form 483 revealed that there were 222,000 complaints, over 175,000 of which occurred between 2008 to 2017 found by searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black.

272. In the Company's 2019 Annual Report to Shareholders, released on or about January 28, 2020, van Houten said:

> Our Connected Care businesses had a challenging year, even as we retained market share. The businesses posted modest growth, though profitability decreased. The fundamentals remain solid—our Connected Care businesses have leading market positions and good scope for margin expansion. We have taken decisive actions and expect these to gradually become visible in performance in the course of 2020. In January 2020, I appointed Roy Jakobs as the new leader of the Connected Care businesses to further drive the turnaround.

273. On January 28, 2020, the Company released its earnings for the Fourth Quarter of 2019. The release reported that sales increased to EUR 6 billion, with comparable sales growth of

3%, income from continuing operations amounted to EUR 550 million and Adjusted EBITA margin increased to 17.9%. Sleep & Respiratory Care again recorded steady sales. For the Connected Care business, the Company reported sales of EUR 1,354 for the quarter. "Comparable sales growth was 2%, with mid-single-digit growth in Monitoring & Analytics and flat sales in Sleep & Respiratory Care." For the full year 2019, the Company reported sales from the Connected Care businesses of EUR 4,674. "Comparable sales growth" for the year "was 3%, with low-single-digit growth in Sleep & Respiratory Care."

274. On January 28, 2020, the Company hosted an earnings call with investors, during which the Company discussed Philips' earnings and financial results for the Fourth Quarter of 2019 (the "4Q2019 Earnings Call"). During the 4Q2019 Earnings Call, Bhattacharya stated that "sales for the Connected Care business grew 2% in the fourth quarter[.] . . . The Sleep & Respiratory Care business comparable sales was [*sic*] in line with Q4 2018, on the back of overall tough comparables as well as soft ventilation market. The sales for Connected Care grew 3% for the full year."

275. During the 4Q2019 Earnings Call, van Houten said:

> On the Sleep & Respiratory Care side, we have seen good performance in the sleep business in the fourth quarter. In fact, through the year, while the hospital—the home ventilation business was—had a slowdown due to the changes in the reimbursement process and we consequently sold more of the oxygen business that had a lower margin. And we expect that reimbursement situation to ease up in the course of 2020. The sleep business will continue with strong momentum.
>
> Of course, I'm very much aware that on the mask side, 2018 was a very strong year for us. 2019 became a stronger year for our competitor, but we will fight back, and we think that we are also there looking at an increased momentum during the year.

276. During the 4Q2019 Earnings Call, in response to an analyst's request for "a bit more detail on" what Philips "would specifically be focusing on in Connected Care." In response, van Houten said:

> I bring to recollection that Connected Care has 2 very strong businesses with one, Sleep & Respiratory Care, the other one, Monitoring and Analytics. We already saw an improving momentum in Monitoring & Analytics. We expect an improving momentum in Sleep & Respiratory Care. Once you have those 2 fully engaging and performing, that will give a great platform of margin expansion.

277. The statements referenced in ¶¶ 272-76 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(xiii) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products, which were being hidden from the public, and the risk that there would not be an "improving momentum in Sleep & Respiratory Care" was great. Indeed, the FDA Form 483 revealed that there were 222,000 complaints, over 175,000 of which occurred between 2008 to 2017 found by searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black.

278. On February 25, 2020, the Company filed its Annual Report on SEC Form 20-F for the year ended December 31, 2019 (the "2019 20-F"). In the 2019 20-F, the Company stated:

279. In a section containing a letter from van Houten to Philips' shareholders, the 2019 20-F stated, in relevant part:

> As we step up our transformation, we continue to be guided by our three-pronged strategic roadmap: *Better serve customers and improve quality; Boost growth in core business; Win with solutions along the health continuum*. We are making steady progress on our commitment to quality and operational excellence, as demonstrated by improving quality indicators, customer Net Promoter Scores and lower waste. The standardization and digitalization of internal processes, levering the Philips Integrated IT landscape, is leading to higher productivity and agility. Our continued focus on boosting growth in the core has delivered market share expansion in the Diagnosis & Treatment segment in particular. Revenues from solutions, long-term contracts and service business models – including new business models, such as software-as-a-service, pay-per-user and technology managed services – now stand at over one third of sales.

(emphasis in original.)

280. Further, in a section discussing the Company's strategy and business, the 2019 20-F stated, in relevant part:

> With our global reach, deep clinical and technological insights and innovative strength, we are uniquely positioned in 'the last yard' to consumers and care providers, delivering:
>
> - connected products and services supporting the health and well-being of people
> - integrated modalities and clinical informatics to deliver precision diagnosis
> - real-time guidance and smart devices for minimally invasive interventions
> - connected products and services for chronic care.

In that same section, the 2019 20-F listed "[b]etter serve customers and improve quality" as one of the Company's "key strategic imperatives and value creation objectives," and stated that this imperative was driven by "[i]mprov[ing] customer experience, quality systems, operational excellence and productivity."

281. In addition, in discussing how the Company creates value, the 2019 20-F listed manufacturing as one of the six forms of capital that Philips "draws upon for its business activities," stating, in relevant part, "[w]e apply Lean techniques to our manufacturing processes to produce high-quality products. We manage our supply chain in a responsible way."

282. Moreover, in discussing the Company's Connected Care businesses, the 2019 20-F stated, in relevant part:

> Spanning the entire health continuum, the Connected Care businesses are tasked with improving patient outcomes, increasing efficiency and enhancing patient and caregiver satisfaction, thereby driving towards value-based care. Our solutions build on Philips' strength in verticals (monitoring & analytics, sleep & respiratory care, and therapeutic care) and horizontals (population health management and connected care informatics) to improve clinical and economic outcomes in all care settings, within and outside the hospital.
>
> Philips has a deep understanding of clinical care and the patient experience that, when coupled with our consultative approach, allows us to be an effective partner for transformation, both across the enterprise and at the level of the individual clinician. Philips delivers services that take the burden off hospital staff with

optimized patient and data flow, predictive analytics, improved workflow, customized training and improved accessibility across our application landscape.

***

- **Sleep & Respiratory Care**: Sleep offerings span from consumer sleep solutions, including those for disease-state sleep such as obstructive sleep apnea, to end-to-end solutions that encompass consumer engagement, diagnostics, people-centric therapy, cloud-based connected propositions and care management services. Respiratory offerings include COPD care management with digital and connected solutions; Hospital Respiratory Care (HRC) provides invasive and non-invasive ventilators for acute and sub-acute hospital environments; Home Respiratory Care supports the home care environment.

283. Moreover, in the 2019 20-F, the Company stated:

Quality, Regulatory Compliance and Integrity
Our business success depends on the quality of our products, services, and solutions, and compliance with many regulations and standards on a global basis. . . .

. . .

Responsibility for Quality & Regulatory Compliance rests with the Chief Quality & Regulatory Officer, who reports operationally to the Chief Operations Officer and – for regulatory matters – directly to the Chief Executive Officer.

Quality
Philips is committed to delivering the highest quality products, services and solutions compliant with all applicable laws and standards. We are investing substantially in embedding quality in our organizational culture. We will continue to raise the performance bar. Quality is an integral part of the evaluation of all levels of management. With consistency of purpose, top-down accountability, standardization, leveraging continuous improvement we aim to drive greater speed in the adoption of a quality mindset throughout the enterprise.

Regulatory Compliance
Philips actively maintains Quality Systems globally that establish standards for its product design, manufacturing and distribution processes; these standards are in compliance with Food and Drug Administration (FDA)/International Organization for Standardization (ISO) requirements. Our businesses are subject to compliance with regulatory pre-marketing and quality system requirements in every market we serve, and to specific requirements of local and national regulatory authorities including the US FDA[.] . . .

We have a growing portfolio of regulated products in our Personal Health and Sleep & Respiratory Care businesses.

[. . .]

Compliance risks

> *Philips is exposed to non-compliance with the various regulatory regimes their products and services are subject to, including data privacy requirements.*
>
> Philips' products and services are subject to regulation . . . by various government and regulatory agencies (e.g. FDA (US)[.]). . . . Philips' increased focus on the healthcare sector increases its exposure to such highly regulated markets[.] . . . [C]onditions imposed by regulatory authorities ***could*** result in product recalls or a temporary ban on products and/or stoppages at production facilities, or increased implementation costs in the roll-out of products and services or claims for damages. The risk also exists that ***product safety incidents or user concerns***, as in the past, ***could trigger*** business ***reviews by the FDA or other regulatory agencies***: if failed, these reviews ***could*** lead to business interruption, which in turn ***could*** adversely affect Philips' financial condition and operating results, as well as our reputation and brand. . . . Non-compliance with any applicable laws and regulations, including with respect to product regulation and data privacy, ***may*** result in penalties, cost of proceedings and litigation, and repair costs, any of which ***may*** have a material adverse effect on Philips' financial condition and results of operations.

284. In the 2019 20-F, the Company reported that 47% of its sales from the Connected Care businesses were from Sleep & Respiratory Care. Reporting on the Connected Care businesses, the Company stated: "In 2019, sales amounted to EUR 4,674 million, 8% higher on a nominal basis compared to 2018. Excluding a 4.6% positive currency effect and consolidation impact, comparable sales increased by 3%, with low-single-digit growth in Sleep & Respiratory Care and Monitoring & Analytics."

285. The statements referenced in ¶¶ 278-84 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(xiii) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products, which were being hidden from the public, and the Company was not adequately reporting risks to the market. Indeed, the FDA Form 483 revealed that there were 222,000 complaints, over 175,000 of which occurred between 2008 to 2017 found by searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black.

286. On April 14, 2020, Philips issued a press release entitled, "Philips details plans to increase its hospital ventilator production to 4,000 units/week by Q3 2020, and introduces its new Philips Respironics E30 ventilator with an immediate production of 15,000 units/week." The press release stated, in relevant part:

> [Philips] today provided an update on its plans to double the production of its hospital ventilators by May 2020 and achieve a four-fold increase by the third quarter of 2020. This plan builds on Philips' initial production increase in the first three months of the year, which already enabled the supply of additional ventilators—that are critical for the treatment of COVID-19 patients—to hospitals in the most affected regions in China, southern Europe and the US. To further address the huge global demand, Philips introduced its new Philips Respironics E30 ventilator, a versatile and easy-to-use non-invasive and invasive ventilator, which has been designed for large scale production.
>
> "***In line with Philips' mission, we are fully committed to helping as many healthcare providers as possible diagnose, treat and monitor the growing numbers of COVID-19 patients***," said Frans van Houten, CEO of Royal Philips. "We have been mobilizing as a company to do so since January. The collaboration with our trusted partners Flex and Jabil will rapidly expand our hospital ventilator production capacity, and reinforce the supply chain to enable the ramp up to a production of 4,000 hospital ventilators per week by the third quarter. To complement this, our team has developed the new Philips Respironics E30 ventilator, which can be safely used when there is limited access to a fully featured critical care ventilator. The Philips Respironics E30 ventilator can deliver a range of treatment options, and we will quickly scale its production to 15,000 units per week in April."
>
> * * *
>
> **Introduction of Philips Respironics E30 for emergency use to fill the critical hospital ventilation shortage**
>
> To further address the pressing need for critical care ventilators, Philips has been working closely with leading respiratory physicians and medical device regulators in the U.S. and other countries to develop a readily available ventilator that fills the critical hospital ventilation shortage.
>
> Designed for large scale production by a team deeply experienced in respiratory care, the Philips Respironics E30 ventilator is optimized to treat patients with respiratory insufficiency. This easy-to-use ventilator offers quick set-up and simple operations allowing healthcare providers with a wide range of skill sets to treat and monitor patients. The Philips Respironics E30 can be used non-invasively, as well as invasively, offering the flexibility to adapt to the treatment needs of patients with COVID-19.

287. The statements referenced in ¶ 286 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(xiii) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products and it produced the E30 using the same Foam. Indeed, the FDA Form 483 revealed that there were 222,000 complaints, over 175,000 of which occurred between 2008 to 2017 found by searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black.

288. On April 20, 2020, the Company released its earnings for the First Quarter of 2020. The release reported sales of EUR 4.2 billion, with comparable sales decline of 2%, that income from continuing operations amounted to EUR 42 million, and an Adjusted EBITA margin of 5.9%. Sleep & Respiratory Care recorded double-digit growth. Nevertheless, "[c]omparable sales in the Connected Care businesses increased 7%, with double-digit growth in Sleep & Respiratory Care. Comparable order intake showed a very strong double-digit increase, driven by strong demand for patient monitors and hospital ventilators. The Adjusted EBITA margin increased to 9.8%, mainly due to growth and productivity."

289. On April 20, 2020, Philips issued a press release announcing the Company's earnings results for the First Quarter of 2020 on SEC Form 6-K. The press release stated, in relevant part:

> Comparable sales in the Connected Care businesses increased 7%, with double-digit growth in Sleep & Respiratory Care. Comparable order intake showed a very strong double-digit increase, driven by strong demand for patient monitors and hospital ventilators. The Adjusted EBITA margin increased to 9.8%, mainly due to growth and productivity.
>
> ***
>
> To further address the unprecedented demand for ventilators, Philips introduced the Philips Respironics E30 ventilator for emergency use when a fully featured critical care ventilator is not available. Philips is targeting a production of the new

> ventilator - which has been designed for large-scale production - of 15,000 units per week in April.

290. That same day, Philips hosted an earnings call with investors and analysts to discuss the Company's earnings and financial results for the First Quarter of 2020 (the "1Q2020 Earnings Call"). During the scripted portion of the 1Q2020 Earnings Call, van Houten stated, in relevant part:

> To further address the strong global demand in hospital ventilation, we are rolling out our new Philips Respironics E30 ventilator, a versatile and easy-to-use ventilator for emergency use where there is limited access to a fully featured critical care ventilator. The E30 has been designed for large-scale production and will scale to 15,000 units per week in April. With the strong demand to expand ICU bed capacity, we are also working to significantly increase the production volume of patient monitors.

291. During the 1Q2020 Earnings Call, van Houten also stated:

> To further address the strong global demand in hospital ventilation, we are rolling out our new Philips Respironics E30 ventilator, a versatile and easy to use ventilator for emergency use where there is limited access to a fully featured critical care ventilator. The E30 has been designed for large-scale production and will scale to 15,000 units per week in April.
>
> With the strong demand to expand ICU bed capacity, we are also working to significantly increase the production volume of patient monitors.

292. During the 1Q2020 Earnings Call, Bhattacharya stated: "The sales for the Connected Care businesses grew 7%. Sleep and [R]espiratory [C]are sales grew in the double digits, primarily due to strong shipments of respiratory devices."

293. During the 1Q2020 Earnings Call, in response to an analyst's question about the E30 ventilator, van Houten said:

> [T]he E30 . . . is an adaptation from a bi-plane ventilator, to which we have changed the software, added sensors, added filters, ***so that it is safe and suitable for critical care***. But, as it is a derivative of a bi-plane, it comes from a high-volume platform. That also makes it easier to manufacture at high volumes and without lots of accessories, it would be in the order of magnitude of €2,500.
>
> On how sustainable it is, we think that there will be a peak demand and then it will go down again. This of course depends on what will happen in emerging markets.

> I think that is the big unknown. This could be quite a suitable product for emerging markets, but we are not counting on this being a long lasting, high volume product. Since we are leveraging our other existing production lines for sleep and respiratory care, we would then go back to producing other types of equipment there.
>
> In terms of the order book, most of the orders that we have received are firm orders. I think what we can all observe from the dialogues or from the medical folks is that this pandemic will be with us for quite a long time. It may have its resurgences, therefore we can expect that health systems around the world will want to have some spare capacity in their critical care equipment, in their ICU capacity. Call that stockpiling or call it something else, I think society will demand from these healthcare systems that they are prepared for a resurgence of cases, and therefore I am not that worried that orders would be cancelled.

294. During the 1Q2020 Earnings Call, in response to another analyst's question about the distinction between invasive and non-invasive respiratory care devices and the impact on the Company's revenues, van Houten said:

> You need to have ventilators that measure the distress the patient is in, that can react to that, so there needs to be sensors and analytics. ***Moreover, there needs to be filters adapted to the machine*** to avoid viruses spreading through the exhaust of the machine. Moreover, the insight is that even non-severe cases still need higher saturated oxygen levels to help them with their recovery and a CPAP machine cannot do that. So our E30 and EV300 can all deliver higher oxygen levels as they can be connected to oxygen supplies, whereas the CPAP machine just takes normal air out of the atmosphere and blows it into the lungs, so it is quite a different therapy.
>
> Now, ***the E30, that is derivative of the biplane, comes out of our high-volume production lines. We are redirecting some of the capacity from our Sleep business for that***, but the factory lines that we have in that business we can ramp them quite easily, and therefore we do not see/expect a big impact on our Sleep business. By the way, the Sleep business had a positive growth in the first quarter, which was, of course, rewarding to see. I know that many questions were there with regards to how we are performing in Sleep, so first quarter a positive growth.

295. During the 1Q2020 Earnings Call, in response to an analyst's questions regarding the E30 ventilator, van Houten stated:

> The ***E30 is really targeted to support and augment capacity of hospitals in the crisis.*** It is not intended to replace intensive care ventilators as such, but more ***to support those patients that are already having respiratory distress but are not yet in the intensive care unit.*** The product is just launched, so it is early days to say how much uptake there will be. We expect, certainly, emerging markets to have a strong interest. The ***E30 can support both invasive as well as non-invasive***

> ***ventilation and so it was approved under the FDA emergency regulation, so it is a versatile product and it is at much lower cost***. So early days but we expect high demand, and, as we have shown, we can quickly ramp-up and, if necessary, we can also ramp-down if the product would have less uptake, but at this time we expect a big uptake.

296. The statements referenced in ¶¶ 288-95 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(xiii) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products and it produced the E30 using the same Foam. Indeed, the FDA Form 483 revealed that there were 222,000 complaints, over 175,000 of which occurred between 2008 to 2017 found by searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black.

297. On April 24, 2020, the Company released its earnings for the First Quarter of 2017. The release reported that sales increased to EUR 5.7 billion, with comparable sales growth of 3% in the HealthTech portfolio. Sleep & Respiratory Care again recorded high-single-digit growth.

298. On July 20, 2020, the Company issued a press release announcing the Company's earnings results for the Second Quarter of 2020 on SEC Form 6-K. The Company reported sales of EUR 4.4 billion, with 6% comparable sales decrease, income from continuing operations of EUR 213 million, an Adjusted EBITA margin of 9.5%, and operating cash flow of EUR 558 million. Nevertheless, the press release continued, in relevant part:

> Comparable sales in the Connected Care businesses increased 14%, with double-digit growth in Sleep & Respiratory Care and mid-single-digit growth in Monitoring & Analytics. Comparable order intake more than doubled, driven by strong demand for patient monitors and hospital ventilators. The Adjusted EBITA margin increased to 17.8%, as additional investments to ramp up production were more than offset by operating leverage.

299. On July 20, 2020, the Company hosted an earnings call with investors to discuss Philips' earnings and financial results for the Second Quarter of 2020 (the "2Q2020 Earnings Call"). During the 2Q2020 Earnings Call, Bhattacharya stated:

> The sales of the Connected Care business grew a robust 14% in the second quarter. Sleep and Respiratory Care sales grew double-digit due to strong shipments of respiratory devices. . . .
>
> [W]e have steeply ramped up production of respiratory devices and significantly increased the production of patient monitors in the second quarter. Taking our full COVID-19 portfolio into account, we are investing more than €100 million to meet urgent demand from our customer this year, and we anticipate a high volume of shipments in the second half of the year to fulfil[l] the orders we have on hand for these products.

300. During the 2Q2020 Earnings Call, van Houten said:

> We successfully tripled our ventilator production during the quarter, supporting the treatment of patients in the most affected regions of the world and we are on track to achieve the planned fourfold increase to 4,000 units per week in July.
>
> [. . .]
>
> [There was] a strong 14% comparable sales growth in the Connected Care businesses in the period. Comparable equipment order intake grew a robust 27% driven by the strong demand for our . . . hospital ventilators[.] . . .
>
> [. . .]
>
> [C]omparable order intake in Connected grew by 167% with very strong growth seen across the world. The demand for hospital ventilators increased multifold[.]

301. During the 2Q2020 Earnings Call, van Houten said: "[M]onitor[s] and ventilators are both high-margin—gross margin businesses. Of course, it greatly contributes to operational leverage."

302. During the 2Q2020 Earnings Call, in response to an analyst's questions about the Company's sales growth, van Houten said:

> ***In the third quarter, we will see a strong contribution from Connected Care***. We have a big order book of monitors and ventilators that we will continue to deliver. We have mentioned that we have been successful in ramping our production to approximately fourfold by July, now, currently. And it will take us many months to deliver that order book. So strong positive growth on Connected Care.

303. During the 2Q2020 Earnings Call, in response to an analyst's questions as to whether the Company's revenues from the Sleep & Respiratory Care business were short-term or long-term, van Houten said: "The realisation that COVID is going to be with us for at least two years, and that more capacity needs to be built—that realisation I think is top of mind of healthcare ministers. And so after the initial wave of kind of crisis demand, I think we will see an ongoing demand to build stockpiles, to build more capacity and have you know, a higher ICU bed availability, just to be safe."

304. During the 2Q2020 Earnings Call, in response to another analyst's questions as to whether the Company's revenues from the Sleep & Respiratory Care business were short-term or long-term, van Houten said:

> [T]he Connected Care platform that we talked about, so often—we now see a strong interest in that. I refer to the Veterans Administration—Veterans Affairs giving us a 10-year contract[.] . . . Therefore even if let's say the initial peak in Connected Care will start tapering off, and also on ventilators that will happen, then we are working very hard to get the new babies, the new areas to grow up quickly and take over from there and also then to deliver on some of the promises that we have been making around Connected Care.

305. During the 2Q2020 Earnings Call, in response to an analyst's questions about the Company's E30 ventilator, van Houten said:

> [T]he E30 ventilator was approved under the emergency approval of the FDA. It was a great accomplishment. What we've also learned is that not every government in the world is comfortable with that emergency approval. And several governments still give preference to the Trilogy Evo and the E300 ventilators and the V60 ventilators, which are truly intensive-care hospital ventilators, over the E30. Right. And of course, those have a much higher sales price. Therefore, if you don't mind so much that they give preference to the more sophisticated ventilators.
>
> So the E30 was launched; we immediately got orders in April, tens of thousands. And that's where we are, currently. I think there's still opportunity, perhaps for the emerging markets to pick that up further, although, also in emerging markets, we see the strong interest in the E300 in particular.

306. During the 2Q2020 Earnings Call, in response to an analyst's questions about the Company's representations about its production capacity, van Houten said:

> [T]here are still orders coming in. So that's back to the discussion, you know, first wave of the emergency response, subsequently waves of building infrastructure that is still going to come, and emerging markets are also ordering as we speak. It's just that the visibility of the backlog is about two quarters at the moment, and with capacity increased, our response to delivering on those orders has greatly improved. ***By the way, that 4X will be achieved by the end of July***. So we're almost there.

307. During the 2Q2020 Earnings Call, in response to an analyst's questions about the Company's representations about its ability to secure supply contracts for the ventilators, van Houten said:

> Let's say the ventilators do not always get service contracts immediately. And certainly, during this emergency response, the procurement people at hospitals were just scrambling to get their hands on the ventilators. So we are following that up with a big effort to also offer services, as well as even stockpile maintenance services, because I think what some governments discovered is that they had some stockpile, but it was out of date, and therefore it was not completely useful. We are, to say, extending our technology managed service line to also extend to ventilator program.

308. During the 2Q2020 Earnings Call, in response to an analyst's questions as to whether the Company's revenues from the Sleep & Respiratory Care business were short-term or long-term, Bhattacharya said: "[W]e booked the big US orders in April, so if you take that out, I think the order intake growth is still pretty solid both in monitoring and in ventilators. So no big decline through the quarter."

309. During the 2Q2020 Earnings Call, in response to an analyst's question about the E30 production ramp-up, Bhattacharya said:

> [T]he E30 is basically a modified BiPAP. So while we said we ramp up production to the 15,000, . . . that was a flexible capacity, together with our BiPAP capacity. So we are producing to order now and, you know, we have sold a couple of tens of thousands of units. So it's not that it hasn't, but we are not stuck with high inventories or anything, because that is a thing that we can flex together with our BiPAP capacity. So, so far so good and, like Frans said, it's an emergency ventilator. And if there is future demand in emerging markets, we still have the

> ability to ramp that up very quickly, you know, but we don't mind selling the E300. A more sophisticated unit.

310. The statements referenced in ¶¶ 297-309 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(xiii) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products and it was continuing to promote its products, including the E30 ventilator, as if they were definitely safe, despite the Company's ongoing CAPA investigating their safety. Indeed, the FDA Form 483 revealed that there were 222,000 complaints, over 175,000 of which occurred between 2008 to 2017 found by searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black.

311. In an interview with *Bloomberg* released online on September 15, 2020,[9] van Houten specifically promoted the actions Philips took during the pandemic. He stated:

> Philips is an innovation company. . . Innovators should serve the unmet needs of the world. . . I believe in transparency. We are a good path of impacting billions of lives through our innovations and as a result growing the company faster. . . Back in early March when the whole world became panicky, we had a conversation to say: 'What have we seen in china? What have we seen in Italy?' Clearly the demand for acute care and equipment and software and informatic solutions is going to rise dramatically and we said it's our purpose to improve people's lives through innovation. So we are going to go all out to see whether we can increase capacity to see if we can respond to the need for ventilators and patient monitors . . . We decided in March to invest EUR 100 to build a four-fold manufacturing increase so we could meet demand. . . And we took all the suppliers in the supply chain to help out. And it was amazing because people were so motivated to improve people's lives and risks that people worked day and night to make that happen. So by June already we had achieved our four-fold increase in capacity.

312. The statements referenced in ¶ 311 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(xiii) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its

[9] Available at https://www.bloomberg.com/news/videos/2020-09-15/philips-ceo-van-houten-on-company-s-commitment-to-climate-action-video.

products and it was continuing to promote its products, including the E30 ventilator, as if they were definitely safe, despite the Company's ongoing CAPA investigating their safety. Specifically, van Houten promoted the Company as a pandemic savior because, in part, the Company produced a new ventilator to help hospitals – the same ventilator that Defendants knew or were reckless in not knowing of the ongoing, undisclosed risk that the product would later need to be recalled for failure to meet the requisite product safety regulations. Indeed, the FDA Form 483 revealed that there were 222,000 complaints, over 175,000 of which occurred between 2008 to 2017 found by searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black.

313. On October 19, 2020, the Company issued a press release announcing the Company's earnings results for the Third Quarter of 2020 on SEC Form 6-K. The Company reported sales of EUR 5.0 billion, with a 10% comparable sales growth, that income from continuing operations increased to EUR 341 million, that Adjusted EBITA margin improved to 300 basis points to 15.4%, and that operating cash flow increased to EUR 770 million. The press release went on to state, in relevant part, that:

> Comparable sales in the Connected Care businesses increased 42%, with double-digit growth in Monitoring & Analytics and Sleep & Respiratory Care. Excluding the partial termination of the ventilator contract with HHS, comparable order intake showed a double-digit increase, with strong growth across all businesses. The Adjusted EBITA margin increased to 27.1%, driven by higher volumes and operating leverage.

314. That same day, Philips hosted an earnings call with investors and analysts to discuss the Company's earnings results for the Third Quarter of 2020 (the "3Q2020 Earnings Call"). During the scripted portion of the 3Q2020 Earnings Call, van Houten stated, in relevant part:

> Connected Care grew a very strong 42% in the quarter, driven by the high volume of shipments to fulfill the order for patient monitors and respiratory care. . . .

> Comparable equipment order intake grew 3% in the quarter, excluding the impact from the unexpected partial termination of the April 2020 contract with HHS which was communicated in August. Quarter intake growth was driven by the demands for patient monitors, ***hospital ventilators***, computer tomography and portable ultrasound systems. Customer response to our innovative products and solutions remains very positive and we have—we expect to have a continued increasing market share in the professional healthcare market.

315. During the 3Q2020 Earnings Call, Bhattacharya said:

> The sales for Connected Care business grew a very strong 42% in Q3, driven by shipments of patient monitors and respiratory care solutions. As mentioned by Frans, we have ramped up the production of these devices to meet urgent demand and fulfil[l] the orders we have on hand for these products.

316. During the 3Q2020 Earnings Call, Bhattacharya said:

> [A]s mentioned by Frans, order intake grew 3% in Q3, excluding the impact on the partial cancellation of the H[H]S contract. This based [*sic*] on double-digit growth seen in the first half of the year, resulting in double-digit growth year-to-date and a strong order book for the Group as depicted on page 29 of our IR booklet.
>
> For reference, if the booking and cancellations of the HHS deal had taken place in the same quarter, so assuming that the booking and cancellation had happened in Q4, the order intake growth for Q2 would have been high-single digit compared to the 27% reported previously.
>
> Comparable order intake in Connected Care grew by 26% in the quarter, excluding the impact from the HHS contract, with double-digit growth across all businesses.

317. During the 3Q2020 Earnings Call, in response to an analyst's questions about the impact of the HHS contract cancellation on the Company's profits, van Houten said:

> [W]e had approximately 30,000, or so, ventilators in 2019 and a seven-fold increase this year, in which the cancellation of the 30,000 by the US takes a bite out of that. But it is still a very sizeable step-up versus 2019.
>
> It's the expectation that the hospital ventilator market will return to a 2019 level in 2021. . . . [W]e are not the only one that is affected, but the way, by partial cancellation; also two other vendors it happened to them [*sic*].
>
> And still, as Abhijit said, we still see orders coming in, in the fourth quarter. There are still countries in the world that are under-equipped when it comes to acute care, and depending on how COVID-19 develops, it could well be that we will also see stockpile programmes coming up from various governments. It's, for example, being debated in the European Commission. . . .
>
> [. . .]

> I mentioned hospital respiration to go down, but then the home ventilation and sleep apnoea [*sic*] market will strongly recover, right, and therefore, we can be—and then the tele-health market will also get a boost, so we can expect Connected Care to be in that 5-6% bracket in 2022 after we have compensated for the spike. And you heard Abhijit say basically that if you think about Connected Care versus 2019, then next year should be in positive growth territory as well. I think first that, we should be able to model that.

318. The statements referenced in ¶¶ 313-17 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(xiii) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products and it was continuing to promote its products, including the E30 ventilator, as if they were definitely safe, despite the Company's ongoing CAPA investigating their safety. Indeed, the FDA Form 483 revealed that there were 222,000 complaints, over 175,000 of which occurred between 2008 to 2017 found by searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black.

319. In the 2020 Annual Report to Shareholders, released on or about January 25, 2021, van Houten said:

> Faced with the COVID-19 pandemic, Philips demonstrated strength and agility, working intensely together with healthcare providers to cope with the challenges for both acute and regular healthcare. At the same time we continued to support people with their personal health. More than ever, we have the potential to accelerate the transformation of healthcare with our innovative solutions.
>
> [. . .]
>
> In 2020, Philips again demonstrated its relevance in bringing meaningful innovation to improve people's health and well-being, as we responded to the COVID-19 pandemic. As a company, we continue to focus on delivering against our triple duty of care—meeting critical customer needs, safeguarding the health and safety of our employees, and ensuring business continuity.
>
> . . . We significantly increased production of critical care ventilators, provided ICU monitoring & analytics solutions, and rolled out telehealth solutions to relieve the pressure on scarce resources. . . .
>
> In parallel, we continued to support health systems with delivery of regular care, entering into multiple long-term strategic partnerships—all featuring result-oriented business models—to transform healthcare by enhancing patient care

> and improving productivity. We also found new ways to serve consumers seeking to live a health life, prevent disease and proactively manage their own health. In total, our products and solutions improved the lives of 1.75 billion people in 2020, including 207 million people in underserved communities.
>
> [. . .]
>
> *Our performance in 2020*
> COVID-19 impacted every part of our business in 2020. Nevertheless, despite the challenging circumstances, we were able to execute our plans and return to growth in the second half of the year. . . .
>
> [. . .]
>
> Our Connected Care businesses posted exceptional growth, fueled by COVID-19-related demand for our hospital ventilation and monitoring & analytics solutions.

320. On January 25, 2021, Philips issued a press release announcing the Company's Q4 and full year 2020 results on SEC Form 6-K. For the quarter, the Company reported sales of EUR 6.0 million, with 7% comparable sales growth, that income from continuing operations increased to EUR 608 million, that the Adjusted EBITA margin improved 110 basis points to 19.0%, and that operating cash flow increased to EUR 1,305 million. The press release continued, in relevant part, that:

> Comparable sales in the Connected Care businesses increased 24% in the quarter, with double-digit growth in Monitoring & Analytics and Sleep & Respiratory Care. Comparable order intake showed a 17% increase, with strong growth across all businesses. The Adjusted EBITA margin increased to 27.2%, due to operating leverage and productivity programs. For the full year, the Connected Care businesses delivered 22% comparable sales growth and an Adjusted EBITA margin of 21.5%.
>
> ***
>
> Philips' ongoing focus on innovation and partnerships resulted in the following key developments in the quarter and the year:
>
> ***
>
> Expanding its range of patient-centric solutions for the home, Philips launched the BiPAP A40 EFL non-invasive ventilator. With this introduction, Philips is extending its respiratory care solutions with a new ventilation therapy feature to treat COPD patients with expiratory flow limitation (EFL) with targeted therapy to reduce symptoms and increase their comfort while sleeping.

321. That same day, Philips hosted an earnings call with investors and analysts to discuss the Company's earnings and financial results for the Fourth Quarter of 2020 (the "4Q2020 Earnings Call"). During the 4Q2020 Earnings Call, van Houten stated, in relevant part:

> [. . .] I am pleased that we have recorded comparable sales growth of 7% in Q4. Connected Care grew a very strong 24%, driven by the demand for patient monitors and respiratory care. Our Diagnosis & Treatment businesses delivered encouraging sequential improvement and returned to growth with a 1% comparable sales increase. Sales for Personal Health grew a solid 5%.
>
> Comparable equipment order intake grew 7% in Q4, with double-digit growth in Connected Care and 3% growth in Diagnosis & Treatment. This was driven by strong demand for our patient monitors, hospital ventilators, radiology informatics, computed tomography, x-ray and ultrasound systems.
>
> ***
>
> Now I would like to provide some color on some of our initiatives to respond to customer needs and support healthcare professionals and consumers. In the quarter, we expanded our range of patient-centric solutions for the home with the launch of the BiPAP A40 non-invasive ventilator. With this introduction, we extend our respiratory care solutions with a new ventilation therapy feature to treat COPD patients with expiratory flow limitation, or EFL.

322. During the 4Q2020 Earnings Call, van Houten stated:

> Connected Care grew a very strong 24%, driven by the demand for patient monitors and respiratory care. . . . Comparable equipment order intake grew 7% in Q4 with double-digit growth in Connected Care[.] . . . This was driven by strong demand for . . . hospital ventilators[.] . . .
>
> Customer response to our innovative products and solutions remains very positive, resulting in market share gains and strong year-end order book in both Connected Care and Diagnosis and Treatment.

323. During the 4Q2020 Earnings Call, Bhattacharya stated, in relevant part:

> The sales for Connected Care businesses grew a strong 24% in Q4 . . . In the full year, comparable sales for Connected Care grew 22% with double-digit growth in both Monitoring & Analytics and Sleep & Respiratory Care. Order intake for Connected Care grew strong double digits in the full year.

324. During the 4Q2020 Earnings Call, in response to an analyst's question: "[H]ave you been able to secure all the service contracts for all the new ventilator sales you realized last year[,]" van Houten said:

> We are working very hard to secure service contracts for this vast installed base that is now in place. We are also working with governments who have stockpile programmes to remind them that just having it in a stockpile is not a recipe for success; you need to maintain it. I think this was a lesson also observed in the United States.
>
> I would say still some potential there to do more but definitely possible. Now, in any case, it usually takes a year between a delivery and a service contract to have an impact on Philips because the first year is like warranty and everything else. But we're working on it.

325. The statements referenced in ¶¶ 319-24 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(xiii) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products and it was continuing to promote its reaction to the pandemic, which included introducing a new ventilator that Defendants knew, but did not disclose, would need to be recalled for failure to meet the requisite product safety regulations. Indeed, the FDA Form 483 revealed that there were 222,000 complaints, over 175,000 of which occurred between 2008 to 2017 found by searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black.

326. On February 23, 2021, the Company filed its Annual Report on SEC Form 20-F for the year ended December 31, 2020 (the "2020 20-F"). Appended to the 2020 20-F as exhibits were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by the Individual Defendants, attesting that "[t]he [2020 20-F] fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and information contained in the [2020 20-F] fairly presents, in all material respects, the financial condition and results of operations of the Company."

327. In the 2020 20-F, for 2020, Defendants reported net income of $1.187 billion, or $1.29 per diluted share, on revenue of $19.535 billion.

328. In a section containing a letter from van Houten to Philips' shareholders, the 2020 20-F stated, in relevant part:

> In 2020, Philips again demonstrated its relevance in bringing meaningful innovation to improve people's health and well-being, as we responded to the COVID-19 pandemic. As a company, we continue to focus on delivering against our triple duty of care – meeting critical customer needs, safeguarding the health and safety of our employees, and ensuring business continuity.
>
> ***
>
> The developments of the past year validate our strategy to innovate the provision of care along the health continuum – putting the patient at the center, improving diagnosis and treatment pathways, enabling the integration of care across care settings, and increasing care provider productivity. At the same time, we help consumers to live healthier lifestyles and to cope with chronic disease. Increasingly, we are able to connect home and hospital care through telehealth platforms. This approach is resonating more strongly than ever.
>
> ***Customers appreciate the comprehensive and strategic view we take of the future of health and healthcare. They want innovative solutions – smart combinations of systems, devices, informatics, data and services – that can help them deliver on the Quadruple Aim of better health outcomes, improved patient experience, improved staff experience, and lower cost of care.*** Given the learnings from COVID-19, they are especially keen to discover how we can support care outside the hospital.
>
> ***
>
> ***Our Connected Care businesses posted exceptional growth***, fueled by COVID-19-related demand for our hospital ventilation and monitoring & analytics solutions.
>
> ***
>
> We aim to drive customer preference by getting even closer to our customers and consumers, making Philips easier to do business with, and further improving our quality, operational excellence and productivity. To do this, we are driving the digital transformation in every area of our business, leveraging our integrated IT landscape – from the way we connect and engage with our customers and consumers to seamlessly connecting our solutions, e.g. to enable remote servicing and upgrades.

329. Further, in discussing the Company's Connected Care businesses, the 2020 20-F stated, in relevant part:

> Spanning the entire health continuum, the Connected Care businesses help broaden the reach and deepen the impact of healthcare with solutions that leverage and unite devices, informatics, data and people across networks of care, to enable our

customers to deliver on the Quadruple Aim – better health outcomes, improved patient experience, improved staff experience, and lower cost of care.

***

- **Sleep & Respiratory Care**: Philips' cloud-based sleep and respiratory patient management solutions enable the care of more than 10.5 million connected patients, driving adherence, reimbursement and remote patient management. From consumer sleep solutions, including those for disease-state sleep such as obstructive sleep apnea, to end-to-end solutions that encompass consumer engagement, diagnostics, people-centric therapy, cloud-based connected propositions and care management services. The COVID-19 crisis has put respiratory care at the top of the list for delivering critical and chronic care to patients. Respiratory offerings include COPD (Chronic Obstructive Pulmonary Disease) care management, with digital and connected solutions; Hospital Respiratory Care provides invasive and non-invasive ventilators for acute and sub-acute hospital environments; Home Respiratory Care supports chronic care management in the home.

330. In addition, the 2020 20-F contained substantively similar statements regarding the Company's manufacturing capabilities, product design quality, and regulatory compliance as discussed, *supra*, ¶¶ 282-83.

331. In the 2020 20-F, the Company stated:

Quality & Regulatory
Our business success depends on the quality of our products, services and solutions, and compliance with many regulations and standards on a global basis. . . .

. . .

Regulatory Compliance
Philips actively maintains Quality Systems globally that establish processes for its product design, manufacturing and distribution processes; ***these standards are in compliance with Food and Drug Administration (FDA)/International Organization for Standardization (ISO) requirements***. Our business are subject to compliance with regulatory pre-marketing and quality system requirements in every market we serve, and to specific requirements of local and national regulatory authorities including the US FDA[.] . . .

. . .

We have a growing portfolio of ***regulated products*** in our Personal Health and ***Sleep & Respiratory Care*** businesses. . . .

. . .

. . . Failing to comply with the regulatory requirements can have significant legal and business consequences. . . .

. . .

Compliance risks

Philips is exposed to non-compliance of its products and services with various regulations and standards including quality, product safety and data privacy.

Philips operates in a highly regulated product safety and quality environment and its products and services, including parts or materials from suppliers, are subject to regulation by various government and regulatory agencies (e.g. FDA (US)[.]). . . .

. . . Non-compliance with conditions imposed by regulatory authorities ***could*** result in product recalls, a temporary ban on products, stoppages at production facilities, remediation costs, fines or claims for damages. Product safety incidents or user concerns, as in the past, ***could trigger business reviews by the FDA or other regulatory agencies, which, if failed, could trigger these impacts.***

. . .

Non-compliance ***could*** adversely impact Philips' financial condition or operating result through lost revenue and cost of any required remedial actions, penalties or claims for damages. These issues ***could*** also further negatively impact Philips' reputation, brand, relationship with customers and market share.

332. In the 2020 20-F, the Company reported that 49% of its sales from the Connected Care businesses were from Sleep & Respiratory Care, meaning over 8% of Company income from sales in 2020 were from sales of the at-issue Devices. 2020 20-F at §6.3.2. Reporting on the Connected Care businesses, the Company stated: "In 2020, sales amounted to EUR 5,564 million, 19% higher than in 2019 on a nominal basis. Excluding a 2.9% negative currency effect and consolidation impact, comparable sales increased by 22%, with double-digit growth in both Monitoring & Analytics and Sleep & Respiratory Care, as our innovations in these therapeutic areas were able to hep our customers combat the pandemic."

333. The statements referenced in ¶¶ 326-32 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(xiii) and (xvii), particularly because Philips had already received multiple complaints about the Foam being used in its products and Defendants were not properly disclosing these known risks to the public. Indeed, the FDA Form 483 revealed that there were 222,000 complaints, over 175,000 of which occurred

between 2008 to 2017 found by searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black.

334. On April 26, 2021, Philips issued a press release announcing the Company's financial results for the First Quarter of 2021 on SEC Form 6-K. The Company reported sales of 3.8 billion, with 9% comparable sales growth, that net income amounted to EUR 40 million, and that the Adjusted EBITA margin improved 390 basis points to 9.5%. The Company reported sales from the Connected Care businesses of EUR 1,161. "Comparable sales growth was 7%" across the Connected Care businesses, "with double-digit growth in Hospital Patient Monitoring, partly offset by a mid-single-digit decline in Sleep & Respiratory Care." Nevertheless, "Adjusted EBITA increased by EUR 40 million" for the Connected Care businesses, "resulting in a margin of 12.8%, mainly driven by sales growth and productivity measures." In the press release, van Houten said:

> Regretfully, we have identified a quality issue in a component that is used in certain sleep and respiratory care products, and are initiating all precautionary actions to address this issue, for which we have taken a EUR 250 million provision.

335. On April 26, 2021, the Company hosted an earnings call with investors to discuss Philips' earnings and financial results for the First Quarter of 2021 (the "1Q2021 Earnings Call"). During the 1Q 2021 Earnings Call, van Houten said:

> Despite the ongoing impact of COVID-19, our performance gained momentum with a strong 9% comparable sales growth and an adjusted EBITA margin increase of almost 400 basis points in first quarter. . . . [O]ur Connected Care businesses delivered 7% comparable sales increase[.] . . . Comparable order intake for the Connected Care businesses decreased as anticipated, following the exceptional growth in Q1 2020, driven by the demand for hospital ventilators and patient monitors.

336. During the 1Q2021 Earnings Call, van Houten said:

> On the regulatory matters, regretfully, we have identified possible risks related to the sound abatement foam used in certain sleep and respiratory care devices currently in use. And this is primarily related to the first generation DreamStation product family. We are in the process of engaging with the relevant regulatory agencies regarding this matter and initiating appropriate actions to mitigate these

possible risks. ***Given the estimated scope of the intended precautionary actions on the installed base, we have taken a provision of €250 million***. I would like to flag that our latest CPAP platform, the DreamStation 2 is not affected as it is of a different design.

337. During the 1Q2021 Earnings Call, an analyst asked about "some of the issues that have been reported by users" of the DreamStation 1 "and whether any of these have been significant? And what does the current provision account for as it relates to the €3-4 million installed base? And whether you expect any short-term impact on sales because of these issues." The analyst also asked about "the broader performance of the sleep business," specifically, "where are diagnosis rates relative to pre-COVID levels, and do you think you're gaining share here?" In response, van Houten said:

> The issue with the DreamStation 1 family and related products come [*sic*] out of our post-market surveillance, where we have picked up reports from users that lead us to do this warning. ***The occurrence rate is very, very low*** and in the last year, it got accelerated because of what we have discovered, the use of unauthorised detergents in cleaning the machine. ***In the US there's quite a lot of locations that have started to use Ozone to disinfect the machine.*** And in fact, that has an impact on the foam used in the machine which makes it degrade. Globally, we have seen some occurrence of that phenomena in high humidity, high temperature environments. ***As I said, the occurrence rate is very, very low, 0.03%*** of [*sic*] the top of my head. Nevertheless being responsible and proactive, we don't want to have this happen and we are going to repair the machines in the field, for which we have taken the provision.
>
> Now, the installed base is ***very high given that Philips is the market leader in sleep apnoea*** [*sic*] ***CPAP devices. And there's several millions out there, a couple of millions out there, and that relates then to the magnitude of the provision***. I hope that scopes that a bit. It is early stage because we wanted to go out immediately and we are, also in parallel then, engaging the regulatory agencies with whom we have to detail out the field safety notice as is customary practice. I want to emphasise this is coming out of our own post-market surveillance actions.
>
> Now, then, you ask, does it have impact on sales? The good thing is that we have launched DreamStation 2. That product is also already authorised in the United States, and is of a different design and is not affected by this component. Other countries, that product is not yet authorised and therefore we were still manufacturing and shipping the Dream series 1. We have, out of precautionary measures, put a temporary stop to the production of those units. Therefore, in relation to your question, can it impact sales on the short term? Yes, it can on a limited basis, because in the ***United States, which is our biggest market and the***

> ***majority of the demand***, we have the Dream series 2 to ship. We are planning to outsource most of the field action to show that we can do it fast and the collaborate [*sic*] third-party capacity, thereby avoiding hindrance to our own manufacturing line.
>
> [. . .]
>
> Then, finally, ***I want to assure everybody on the call that we will compensate for the slowness in the sleep and respiratory care business.*** We still see good demand for a hospital respiration and oxygen concentrators and across Connected Care, we also see strong traction on Patient Monitoring. So, this is also why we kept the guidance on Connected Care the same as we flagged to you before; i.e., high single-digit to low double-digit decline year on year, given the peak of last year.

338. During the 1Q2021 Earnings Call, an analyst asked: "You mentioned the people are using Ozone, which is against the FDA regulations or against your user manual. Why is it your problem then if someone wants to use a cleaning agent that is not even permitted? Why are you taking responsibility for that in those provisions?" Van Houten responded:

> Well, patient safety is always our concern and we have—be very clear to say, first comes the patient. We don't want to debate culpability at this time or who's done it because that doesn't help the patient. And so if there is something to be said about what is the root cause and why did people choose a certain way of cleaning the device, that can be an endless debate. At this time, that should not be the debate. We should just deal with the issue. And then later on, we can sort out better how this cleaning came about.
>
> I mean, if we look around the world, then there's use of Ozone is typically a US issue. And then within the US it is related to certain regions where certain companies have been very active in marketing that message. But that's all, let's say, 20/20 hindsight. The FDA observed this and also put out a safety notice to say, don't use ozone for CPAP machines. Nevertheless, we cannot control that. But we don't want to focus on culpability questions. ***Our prime concern is let's take this small risk out of the market and deal with it proactively***.

339. The statements referenced in ¶¶ 334-38 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i)-(xvii), particularly because Defendants still did not reveal the extent of the complaints and sought to minimize the harm and the blame they shouldered.

340. On September 1, 2021, the Company announced it had started a repair and replacement program for first-generation DreamStation devices in the US. The Company stated:

> ***Philips received authorization from the US Food and Drug Administration (FDA) for the rework of the affected first-generation DreamStation devices***, which consists of replacement of the PE-PUR sound abatement foam with a new material. Philips anticipates rework to commence in the course of September 2021. In addition to the rework, the company has already started replacing certain affected first-generation DreamStation CPAP devices in the US with DreamStation 2 CPAP devices. Philips remains in dialogue with the FDA with respect to other aspects of the recall notification and mitigation plan in the US.

341. The statements referenced in ¶ 340 were materially false and misleading when made for the reasons specified in Paragraph 156 at subdivisions (i) and (xvi), as the FDA would later state the agency was not aware of the potential VOC issue with silicon foam when it authorized this corrective action.

The Truth Slowly Emerges

342. On April 26, 2021, as part of its Quarterly Report for Q1 2021, issued well before the market closed in America, Philips disclosed for the first time, under a section entitled "Regulatory Update," that device user reports had led to a discovery that the Foam posed health risks to its users. Specifically, Philips disclosed that "the [PE-PUR] foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone[], and certain environmental conditions involving high humidity and temperature." As the FDA found, Philips became aware of the issues with polyester polyurethane foam degradation and related field complaints "in at least 2015 or earlier."

343. However, this did not alert the market to the full scale of the problem. In fact, Philips sought to minimize the issue by stating "[t]he majority of the affected devices are in the first-generation DreamStation product family" and mentioning no other product. It also took a provision of only EUR250M, which was solely for repair of units in the field.

344. The Company also hosted an earnings call with investors to discuss the Company's financial and earnings results for the First Quarter of 2021 (the "1Q2021 Earnings Call"). During the 1Q2021 Earnings Call, van Houten stated that "[t]he issue with the DreamStation 1 family and related products come out of our post-market surveillance where we have picked up reports from users that lead us to do this warning."

345. During the 1Q2021 Earnings Call, van Houten stated the Company was "being responsible and proactive" even though "the occurrence rate is very, very low." Van Houten sought to blame the use of ozone products in the cleaning of the machines for the device issues, stating that in other places in the world they had seen foam degradation in "high humidity and high temperature environments" but in the US it was accelerated because of "use ozone to disinfect the machine," which, according to van Houten, caused the Foam to "degrade."

346. During the 1Q2021 Earnings Call, van Houten sought to paint Philips as a responsible corporate citizen, stating: "It is early stage because we wanted to go out immediately and we are also in parallel then engaging the regulatory agencies with whom we have to detail out the field safety notice as is customary practice. ***I want to emphasize this is coming out of our own post-market surveillance actions.***"

347. During the 1Q2021 Earnings Call, van Houten in one breadth stated he did not want "to debate culpability," but then sought to limit Philip's liability by stressing that the use of ozone cleaners might be to blame: "if there is something to be said about what is the root cause and why did people choose a certain way of cleaning the device, then that can be an endless debate . . . if we look around the world, the use of ozone is typically a US issue and then within the US, it is related to certain regions where certain companies have been very active in marketing that method."

348. Van Houten also took steps to minimize the impact of the provision. In response to an analyst question about the EUR250 million provision and whether it was "purely for the field repairs" or whether it also accounted for some litigation risk, van Houten stated:

> Let me say that the amount is related to the field action. ***I've already flagged that any slowness in the business near term is absorbed within the business and compensated elsewhere and therefore not expected to further impact***. This is very early stage so we are acting on the fact that we got a few reports out of the field out of our post-market surveillance and our own test. ***We are taking proactive action here even though the earlier question around ozone and that's not us, that's somebody else. Doesn't matter, we are taking proactive action.*** There are no litigations here at this time. Moreover ***I can say that we have not seen reports of severe user harm. We have seen some reports of irritation, but not severe patient harm***.

349. Nowhere in the call did anyone from Philips mention the many years of complaints the Company had received. Nowhere did they mention any correspondence from the Foam manufacturer or that another Philips division had implemented – years prior – the very change that Philips Respironics was now undergoing.

350. Analysts treated this "update" in the way Philips wanted – by downplaying its significance. For example, on April 27, 2021, a Exane BNP Paribas Research report, which emphasized Philips' increased profitability, stated "the operational/reputational impact [to Philips] should prove limited." It also stressed the supposed proactive nature of the action by Philips (which had "past quality/safety" issues), by stating: "Purely related to field actions and not litigation (proactive action by Philips; ozone not authorized as a cleaning method in the manual; no report of severe user harm)[.] Installed base of >3m units with a very low occurrence rate (approx. 0.03%)[.] Very limited impact foreseen on S&R operations since DreamStation2 (launched in the US) is unaffected by the faulty component and DreamStation 1 is still produced for Europe, but this represents a very minor part of S&R sales/demand[.]"

351. Other analysts, such as Credit Suisse, mentioned only the provision taken, but did not delve into any other impact the reported foam degradation may have on Philips.

352. That said, Philips' stock already began to show the toll the issues with the Sleep & Respiratory Care division were taking – on April 26, 2021, Philips' stock price fell $2.32 per share, or 3.8%, to close at $58.78 per share.

353. However, as time went on, it became clear that Philips' April "company update" was not enough – the Devices would need to be recalled.

354. On June 14, 2021, Philips issued a voluntary recall of certain of its BiPAP and CPAP Devices, as well as mechanical ventilators, after finding that the sound abatement foam used in the Devices can degrade and become toxic, potentially causing cancer (the "June 14 Release"). Specifically, in a press release announcing the recall, Philips stated that the recall was being done "to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in these devices."

355. Philips further claimed the "majority of the affected devices within the advised 5-year service life are in the first-generation DreamStation product family."

356. Philips referenced a "low complaint rate" but only chose to highlight the complaint rate in 2020, which was supposedly 0.03%. There was no explanation of what Philips considered a complaint such that it would be included in the figure provided.

357. The June 14 Release stated: "Philips determined based on testing that there are possible risks to users related to this type of foam. The risks include that the PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals. The foam degradation may be exacerbated by

use of unapproved cleaning methods, such as ozone, and high heat and high humidity environments may also contribute to foam degradation."

358. In the June 14 Release, van Houten is quoted as stating: "We deeply regret any concern and inconvenience that patients using the affected devices will experience because of ***the proactive measures we are announcing today to ensure patient safety . . . Patient safety is at the heart of everything we do at Philips***."

359. The recall notifications broke up the Devices into two categories. First, the recall notification for "Trilogy 100, Trilogy 200, Garbin Plus, Aeris, LifeVent, BiPAP V30, and BiPAP A30/A40 Series Device Models" stated, in relevant part that the Foam "may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user" and "may off-gas certain chemicals." The Company further claimed: "The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone (see FDA safety communication on use of Ozone cleaners), and off-gassing may occur during operation."

360. Philips claimed there had been no reported deaths because of the Foam issues, it stated:

> ***These issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. To date, Philips Respironics has received several complaints*** regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). ***Philips also has received reports of headache, upper airway irritation, cough, chest pressure and sinus infection. The potential risks of particulate exposure include: Irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g. kidneys and liver) and toxic carcinogenic affects. The potential risks of chemical exposure due to off-gassing include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects.***

361. Second, the recall notification for "CPAP and Bi-Level PAP Devices," including the popular DreamStation line and the emergency E30 ventilator, contained a substantively

identical explanation of why the Devices were being recalled, but instead of just stating "off-gassing may occur during operation," for these products Philips stated: "off-gassing may occur during initial operation ***and may possibly continue throughout the device's useful life***." (Emphasis added.)

362. There was no explanation in the June 14 Release offered as to why only these Devices were recalled, when other Devices used the same Foam.

363. The June 14 Release stated: "Philips is providing the relevant regulatory agencies with required information related to the launch and implementation of the projected correction. The company will replace the current sound abatement foam with a new material and has already begun the preparations, which include obtaining the relevant regulatory clearances."

364. Notably, Philips admitted in a June 14, 2021 statement to physicians, "[t]he absence of visible particles does not mean that foam breakdown has not already begun." The Company stated lab analysis revealed the presence of many potentially harmful/carcinogenic chemicals, in the family of isocyanates, including Toluene Diamine, Toluene Diisocyanate and Diethylene glycol. The U.S. Environmental Protection Agency has classified Toluene Diamine as a probable human carcinogen. The U.S. Department of Health and Human Services identified Toluene Diisocyanate as "reasonably anticipated to be [a] human carcinogen." Additionally, the Company told physicians that two "compounds of concern" – Dimethyl Diazine and Phenol 2,6-bis(1,1-dimethylethyl)-4-(1-methylpropyl) - may be emitted from the Foam. These are VOCs, or chemical emissions from foam.

365. On the news of the recall and related health risks, Philips' stock price fell $2.25 per share, or 3.98%, to close at $54.25 per share on June 14, 2021. A *Bloomberg* article titled "Philips Slumps on Recall," stated "Philips shares drop as much as 8.4% before paring losses after the

company recalled ventilation devices used to treat sleep apnea and increased its cost estimate for addressing a defect that may potentially cause cancer. Decline is the steepest intraday since March 2020. Stock trades 4.4% lower as of 9:27 a.m. in Amsterdam." An MT Newswires article titled "Philips Recalls Some Sleep, Respiratory Care Devices Due to Possibly Toxic Foam; Shares Fall" stated "shares fell 4.4% in premarket trading."

366. On July 22, 2021, the FDA identified this as a Class I recall, the most serious type of recall. According to the FDA website, FDA Class I recalls are only identified in "a situation in which there is a ***reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death***."

367. In the July 22, 2021 announcement of the Class I recall status, the FDA stated: "There have been more than 1200 complaints and more than 100 injuries reported" related to the breakdown of the Foam.

368. On July 26, 2021, Philips issued a press release regarding its Q2 2021 results. Van Houten is quoted in the release as stating: "We have mobilized the necessary resources across the company to address the component quality issue in certain of our sleep and respiratory care products. We fully understand the impact that this is having on patients, as their well-being is at the heart of everything we do at Philips . . . We are in discussions with the relevant regulatory authorities to obtain authorization to start deploying the repair kits and replacement devices that we are producing." He then noted that sales growth was otherwise good across the Company, but not in the Sleep & Respiratory Care division.

369. In terms of business segment performance, the release stated: "Comparable sales in the Connected Care businesses decreased 16%, as mid-single-digit growth in Hospital Patient Monitoring was more than offset by a double-digit decline in Sleep & Respiratory Care. . . The

Adjusted EBITA margin amounted to 11.3%, mainly due to the impact in the Sleep & Respiratory Care business."

370. The release also explained that the Company was now taking an additional EUR 250 million reserve – for a total of EUR 500 million reserve in the first half of 2021 – to account for its increase in production, service and repair capacity and the necessary repair/replacement actions.

371. The numbers for the Connected Care business were understandably dire and stated again later on in the release: "Adjusted EBITA decreased by EUR 64 million, resulting in a margin of 12.0%, mainly due to the impact in the Sleep & Respiratory Care business, partly offset by cost savings. Restructuring, acquisition-related and other charges were EUR 576 million, compared to EUR 62 million in the first half of 2020. The first half of 2021 includes a field action provision of EUR 500 million and EUR 38 million of restructuring and acquisition-related charges."

372. The related earnings call further discussed the impact of the recall and the fact that the Company was no longer taking orders for sleep respiratory systems. During the 2Q2021 Earnings Call, Bhattacharya stated: "The sales for the Connected Care businesses declined 16% in Q2, driven by a substantial decline in the Sleep & Respiratory Care business on the back of a very strong Q2 last year, as well as the headwind related to the field action."

373. During the 2Q2021 Earnings Call, van Houten explained that the Company was waiting on FDA approval of its repair plan, but the Company expected to address all devices within a year of regulatory approval of the plan. He also revealed the Company was "currently not taking new orders for sleep therapy systems" because it was prioritizing the field repair actions. He stated that the Company assumed "worst-case scenario" with its recall but was still conducting research and tests.

374. Van Houten stated that Philips did not have any data "indicating that exposure to the particulates or emitted chemicals related to the sound abatement foam will lead to disease," but the Company also could not "exclude" the chance that its Foam would lead to disease.

375. Van Houten then again sought to convince the market that Philips was completely dedicated to product safety, despite the current situation and its past regulatory issues, by stating:

> I also want to talk about the broader context of quality across Philips**.** In the last few years, we have made strong progress in our quality culture and approach, improved design controls, improved post-market surveillance, and improvements in the way that we handle correct and preventative actions. The affected products were designed and have been in full compliance with appropriate standards at the time of release and commercialization, and the component issue was identified through our own post-market surveyance processes.

376. On the 2Q2021 Earnings Call emphasized that the recall was being taken after a "partner," which performs tests for the Sleep & Respiratory Care business, discovered VOCs when analyzing a "relatively small sample size[.]" He stated the Company had since initiated testing on a larger sample and also in different labs.

377. Van Houten explained that, prior to Covid, "the Sleep business [was] €1.1 billion, of which approximately 60% is systems." As the Company ceased to take system orders, that entire amount was "lost revenue."

378. On this news, the stock fell $1.80 per share, or 3.75%, from a close of $47.94 on July 23, 2021 to a close of $46.14 on July 26, 2021.

379. On September 1, 2021, Philips issued an update press release (the "September 1, 2021 Press Release") entitled: "Philips starts repair and replacement program of first-generation DreamStation devices in the US in relation to earlier announced recall notification." The release stated: "More than half of the affected devices in use globally are in the US. The vast majority (>80%) of the registered affected devices in the US to date are in the first-generation DreamStation product family."

380. The September 1, 2021 Press Release further stated that Philips had received FDA authorization for its rework of the impacted DreamStation Devices (and no other devices thus far). Philips explained that it had begun replacing certain first-generation DreamStation CPAP Devices in the US with DreamStation 2 CPAP devices, which the Company had claimed were not dangerous because they utilized a silicone-based foam. It also stated Philips intended to begin "rework" of other first-generation DreamStation Devices that month. It did not specify the "new material" that would be used in the first-generation DreamStation Devices that were being repaired.

381. In October 2021, SoClean, a maker of ozone cleaning products, sued Philips over the statements made in connection with its "Regulatory Update" and recall. SoClean alleged that Philips had tried to blame ozone cleaners when the Philips' products design flaws were clearly to blame.

382. On November 12, 2021, the FDA took the rare step of sharing a comprehensive update to the public regarding its investigation of the recall of certain Philips Respironics ventilators, continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BiPAP) machines (the "November 12 FDA Update"). As part of this update, the FDA disclosed: "In response to the recall, the FDA recently conducted an inspection of a Philips Respironics' manufacturing facility to determine what may have caused or contributed to the foam issues and assess adherence to the agency's requirements for quality manufacturing. FDA inspections are designed to include the review and evaluation of records, staff training, facility operations, medical device production and testing, and the systems in place to ensure product quality. During the inspection, the FDA investigator made several observations that are outlined in an inspection closeout report, also known as an 'FDA Form 483.'" The FDA Form 483 detailed Philips' years

of malfeasance. Among other things, the FDA found that Philips Respironics has "not sufficiently demonstrated that other devices, also containing polyester polyurethane foam, should not be included in [the] ongoing recalls." FDA Form 483 at 1.

383. Philips' recall was not part of a proactive effort after only a few complaints. It was done after years of receiving over 220,000 complaints – complaints they did not fully report to the FDA nor properly investigate in accordance with regulatory standards. Notably, while Philips had previously tried to cast the blame on ozone cleaners for its products' failures, ozone cleaners are not mentioned in FDA Form 483. The November 12, 2021 report was the first time the public was notified that Philips had been misrepresenting its compliance with relevant laws and burying years of complaints about its products.

384. Specifically, in the FDA Form 483, the FDA investigator, Katelyn A. Staub-Zamperini, laid out multiple overarching "observations" about what she found wrong during her inspection of Philips Respironics, Inc., which lasted from August 26, 2021 to November 9, 2021. While the FDA Form 483 does not constitute a final FDA determination of whether any condition is in violation of the Federal Food, Drug, and Cosmetic Act or any of its implementing regulations—and the Company has a right to respond before the FDA takes further action—the allegations in the FDA Form 483 are nonetheless damning.

385. The first observation noted in FDA Form 483 is that "Risk analysis is inadequate." Under the "Observation 1" header, the FDA reported many damaging findings.

386. Under Observation 1, FDA Form 483 stated that Philips had "no documented investigation, risk analysis, or design failure mode effect analysis to" explain why they were recalling some Devices containing the Foam but not others. The FDA Form 483 stated that Philips had not "sufficiently demonstrated that other devices" should not be included in the recalls.

387. On or around November 25, 2015, according to the FDA, the Philips entity in America was made aware that another Philips entity, outside of the country, was performing a preventative maintenance procedure for Trilogy ventilator Devices because of degradation of the Foam in those Devices. But Philips did nothing with regard to the Trilogy devices distributed in America or any of other Devices utilizing the Foam. According to the FDA, "no further investigation, health hazard evaluation, risk analysis, or design review was performed, or documented by" Philips. And Philips did nothing to prevent Foam degradation in the Devices in the field in the US – it did not service the products.

388. Philips was required to perform a risk analysis in an appropriate time frame when they became aware of Foam degradation and/or possible VOC emission concerns but the Company either performed no risk analysis or the one it performed was inadequate. Specifically, the FDA documented at least fourteen instances, assessments, and/or test reports, dated from 04/01/2016 to 01/22/2021, where it was clear the Company "was aware of issues and concerns related to potential foam degradation and/or Volatile Organic Compound (VOC) emissions," but conducted no further risk assessment and did nothing to correct the problem. FDA Form 483 at 3. These include test reports on samples collected based on October 2015 consumer complaints. In other words, Philips tested samples of Foam based on complaints, and documented issues with Foam breakage—including that Foam degradation was worse when the Foam was exposed to high temperature or high humidity—but did not follow-up or pursue corrective measures when these issues were documented.

389. In Observation 1, the FDA also revealed information about silicone foam. The FDA revealed that as part of testing in accordance with ISO guidelines, a Series A CPAP Device utilizing silicon foam failed VOC testing. A test report dated August 24, 2021 reported that in the

performed test there were compounds identified that had carcinogenic/mutagenic properties. Additionally, a related report explained that "pediatric patients would potentially be exposed to higher concentrations of compounds of concern, if they utilized an A Series CPAP Device for sustained periods of time." Silicone foam was being utilized in repair of the recalled Devices – and in Devices that were being used to replace recalled Devices – but apparently Philips did not follow-up with the "risk analysis, health hazard evaluation, or design review" as a result of this documented problem.

390. Under Observation 1, the FDA further discussed the Biological Risk Assessment, dated May 22, 2018, that stated "A total of 17 cases were reported pertaining to the degraded foam in the Trilogy ventilator device." But the FDA's own investigation cast serious doubts on that purported number, and the FDA believed the 2018 assessment was inadequate because it did not consider all known information. Specifically, FDA Form 483 stated:

> Alternatively***, a query of your firm's consumer complaints from 01/01/2008 to current, for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black, resulted in over 222,000 complaints, and over 20,000 of which occurred between 2008 to 2017 and involved Trilogy devices***. Additionally, ***your firm performed a foam related complaint data analysis in April 2021 on complaints confirmed to be related to or involve foam degradation issues. The raw complaint data documents that 30 Trilogy related complaints were received from 2014 to 2017***, and ***1,254 related complaints were received across all products containing the affected foam, from 2014 to 2021***. Therefore, this Biological Risk Assessment and Health Hazard Evaluation are ***not adequate because they do not accurately reflect the known data at that time.***

391. A month later, Philips approved and closed a Health Hazard Evaluation that focused on Foam degradation on Trilogy 100 and Trilogy 200 ventilator Devices. The FDA believed this too was "inadequate." Specifically, the FDA stated that the evaluation "does not accurately reflect the probability and severity of harm related to such foam degradation." The Evaluation documented a "probability of harm" score that can only be used, under the Health Hazard

Evaluation's own instructions, if the harm that caused the investigation was the result of an "isolated incident and no other units are likely to be affected." But this very same evaluation stated that "***Post market surveillance information revealed 17 instances allegedly related to degradation of air inlet path foam***." Seventeen instances—even if there were only seventeen—cannot be characterized as an "isolated incident" and the FDA found no stated rationale from Philips about why this "probability of harm" score was the one documented under these circumstances.

392. The second observation noted in the FDA Report is that "procedures for corrective and preventive action have not been adequately established." Under the "Observation 2" header, the FDA reported many damaging findings.

393. Specifically, under Observation 2, the FDA stated: "No formal CAPA was initiated or implemented, when appropriate, and no verification of effectiveness was performed."

394. Under Observation 2, the FDA Form 483 revealed that there were 222,000 complaints, over 175,000 of which occurred between 2008 to 2017 found by searching the Company's internal database for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black. Additionally, in a 2021 investigation, Philips also identified 110 complaints specifically related to foam degradation from 2014 to 2017. But the Company instituted no formal investigation, nor did it perform a risk analysis related to the complaints.

395. In Observation 2, the FDA revealed that Philips went so far as to contact the Foam supplier as a result of customer concerns about Foam degradation, but still did not report the issue to the FDA or initiate a CAPA. Specifically, an email correspondence to the Foam supplier on October 30, 2015, indicated Philips was aware of Foam degradation issues. A response email from the Foam supplier on August 5, 2016 indicated that concerns about Foam degradation were

warranted. Another email from Philips to the Foam supplier years later, dated April 20, 2018, again confirmed that Philips was aware of Foam degradation issues and had received consumer complaints about Foam breaking apart and debris getting in the airways of Philip's machines. Indeed, internal 2018 emails further indicated the Foam breakdown occurred more frequently in high heat and humidity. Yet no formal CAPA was initiated or implemented and Philips "made the decision not to change the design, and continue to include polyester polyurethane foam, in the Trilogy ventilator platform of devices."

396. In 2018, Philips did finally open at least an informal CAPA. In April 2018, Philips opened an informal CAPA, CAPA INV 0988, due to Trilogy units returned because of degradation of the Foam that was getting into the motor/air path of the Devices. CAPA INV 0988 involved only Trilogy 100 and 200 because the issue supposedly only impacted these Devices. However, Philips received approximately eighty complaints related to degradation for the Foam on non-Trilogy ventilator Devices from 2014 to 2017.

397. That informal CAPA was closed on June 20, 2018 without any formal CAPA ever being initiated. The informal CAPA was not reported to the FDA, but Philips did make an internal change because of it.

398. Philips implemented a "Field Communication" in response to the Foam degradation, which required certain parts of Trilogy models to be replaced as a preventative maintenance procedure. Not only was this preventative procedure not reported to the FDA, but the FDA found that Philips did not internally verify the effectiveness of the procedure.

399. A formal CAPA, CAPA 7211, was not initiated in response to field complaints of foam degradation in the Devices until June 19, 2019.

400. CAPA 7211 was ongoing for years. A foam degradation-related complaint analysis, dated April 9, 2021, part of CAPA 7211, identified 1,254 complaints confirmed to be related to foam degradation from 2014 to April 2021.

401. Under Observation 2, the FDA revealed that even Philips' own internal records were inconsistent. Specifically, as part of CAPA 7211, an April 9, 2021 report identified 1,254 complaints confirmed to be related to foam degradation from 2014 to April 2021, across all affected product platforms. However, it somehow did not include 7 of the 17 complaints documented in CAPA INV 0988. Therefore the April 9, 2021 report very obviously "did not include all applicable complaints known at that time and therefore, was not adequately performed to identify, or detect the severity or magnitude of potential quality issues/concerns."

402. The third observation noted in the FDA Report is that "[d]esign validation did not ensure the device conforms to defined user needs and intended uses." Under the "Observation 3" header, the FDA reported many damaging findings.

403. Specifically, the FDA found under "Observation 3" that when Philips got around to doing a Health Hazard Evaluation, Health Hazard Evaluation ER2227646 V06, which was approved and closed on Jun 15, 2018, it only considered how the products would impact healthy lungs and individuals with healthy bodily functions. However, the intended patients are individuals requiring mechanical ventilation that potentially lack typical and healthy lung and bodily functions. Health Hazard Evaluation ER2227646 V06 does not even consider patients with a tracheostomy, which is part of the relevant patient population.

404. Additionally, the FDA found Health Hazard Evaluation ER2227646 V06 inadequate for the separate reason that it documented "the risk and hazard evaluation based on the use of a humidifier and/or bacterial filter with the use of Trilogy 100 and 200 ventilator devices,

but neither component nor [*sic*] attachment is required for proper use of these ventilators." Health Hazard Evaluation ER2227646 V06 discusses particles needing to pass through the humidifier and additionally notes that "if a bacteria filter was in place, the particulate would not reach the patient," but the ventilators work without either a humidifier or bacteria filter. Both of these are accessories. Therefore, a proper Health Hazard Evaluation should have examined the Devices utilizing only required parts and assessed the health hazard accordingly, but Philips did not do so.

405. The fourth observation noted in the FDA Report is that "[p]rocedures for design change have not been adequately established." Under the "Observation 4" header, the FDA reported many damaging findings.

406. In Observation 4, the FDA took Philips to task for not sufficiently verifying whether any of the Company's proposed fixes would in fact work. The FDA stated: "Specifically, design changes, including changes and updates to preventative maintenance schedules and servicing procedures, were not adequately verified, reviewed, or validated before implementation."

407. The FDA explained how the preventative maintenance servicing procedure instituted in or around June 12, 2018, as a result of CAPA INV 0988, including replacement of parts of the Inlet Air Path Assembly and Removable Air Path Foam, and the intended replacement components "were not verified, reviewed, or validated before implementation."

408. The fifth observation noted in the FDA Report is that "[a] correction or removal, conducted to reduce a risk to health posed by a device, was not reported in writing to FDA." Under the "Observation 5" header, the FDA reported that the preventative maintenance servicing procedure instituted on or around June 12, 2018, as a result of CAPA INV 0988, was simply not reported to the FDA. The FDA Form 483 states that the preventative maintenance servicing

procedure "was initiated due to multiple field complaints and at least 1 Trilogy unit failure, caused by polyester polyurethane foam degradation. This affected foam was later found to be mutagenic, cytotoxic, carcinogenic, and non-biocompatible."

409. The sixth observation noted that "[m]anagement with executive responsibility has not ensured that the quality policy is understood, implemented and maintained at all levels of the organization." Under the "Observation 6" header, the FDA reported many damaging findings.

410. The FDA reported that "firm management, including management with executive responsibility, were aware of potential foam degradation issues concerning CPAPs, BiPAPs, and Trilogy ventilators since at least 01/31/2020, or earlier, and implemented no further corrective actions until April 2021," yet attended meetings at least "since [] 2019" where the foam degradation issues were discussed. FDA Form 483 at 24. The management with executive responsibility included John Frank, the Chief Executive Officer of Philips' Sleep and Respiratory Care Business, also referred to as Philips' Sleep and Respiratory Leader and the Head of Quality. In other words, Philips management was aware of the Foam issues and simply did nothing to ensure the Philips products were not causing harm.

411. The FDA noted that Philips was aware of Foam degradation in 2015 or earlier. The FDA also stated that Philips' Sleep and Respiratory Care Business Leader ("Management With Executive Responsibility") and Head of Quality (Management Representative) —the top echelon at Philips in charge of that business segment—attended all the management review meetings since 2019, where the foam degradation issues were discussed. In attendance at these meetings were at least the Sleep and Respiratory Care Business Leader John Frank (Management with Executive

Responsibility) and Head of Quality (Management Representative)[10]— people who had the power to initiate change. Yet nothing was announced to the public until April 2021.

412. John Frank held a dual role at Philips and at Philips Respironics. Frank's own LinkedIn profile distinguishes between his position at Philips Respironics, Respiratory Care Group between 2004 to 2008 and his position at Philips between 2008 to 2020, making it clear that he also worked at the parent company. *See* https://www.linkedin.com/in/john-frank-8017404/ (last visited October 7, 2022). Zoominfo also states that "John Frank is a Business, Sleep & Respiratory Care At Philips Group Leader at Philips based in Amsterdam, North Holland." *See* https://www.zoominfo.com/p/John-Frank/301772205 (last visited April 6, 2022). According to CW1, Frank was on Philips' Executive Committee. Philips Sleep and Respiratory Care states that Frank is its CEO.[11] Frank was the key person dealing with van Houten, said CW1.

413. As the top executive for Philips' Sleep and Respiratory Care Business, Frank was responsible for a business segment comprising over 21% of Philips' total income from sales in the Personal Health segment, and later comprising over 47% of Philips' total income from sales in the Connected Care segment. During the time relevant time, income from the Personal Health Segment represented over 29% of the Company-wide's income from sales. *See, e.g.*, ¶¶ 115, 117, 133, 139, 147. During the relevant time, income from the Connected Care segment represented over 24% of the Company-wide's income from sales. *Id*. Frank had a key executive role in the corporate decision-making of the Company's Sleep and Respiratory Care business, a cash generator that contributed significantly to Philips' bottom line. As such, he also supplied information about Philips' Sleep and Respiratory Care business for inclusion in public filings and

[10] According to his LinkedIn page, Rodney Mell was Head of Quality at Philips Respironics at all relevant times.
[11] *See* https://twitter.com/philipsresp/status/872543169195462658?lang=en

public disclosures, and/or recklessly disregarded or tolerated Philips' misrepresentations and omissions. Frank knew about the Foam defects but allowed the misrepresentations and omissions to be made, and failed to correct them. Frank was responsible for the performance of Philips' Sleep and Respiratory Care Business, including the performance of the Devices, which fed into Philips' public disclosures, including disclosures related to the performance and quality of the Devices. Frank had ultimate authority over the misstatements, including controlling the content of the misstatements and whether and how to communicate such statements to the public.

414. Frank was directly involved in the daily affairs of Philips at the highest level, directly participated in the management of the Company, and was thus directly involved in controlling the content of the statements at issue. According to CW1, van Houten frequently visited the U.S., usually Pittsburgh or Boston. CW1 explained that "[w]hen it came to things that Frans van Houten wanted his subordinates to do, there were frequent meetings, both live and online." CW1 stated that the foam degradation issues would have been escalated to van Houten given their importance to the Company's bottom line. CW1 stated that John Frank, Eli Diacopoulos, and Mark D'Angelo had frequent meetings with van Houten. Frank also frequently traveled to the Netherlands, where the company's headquarters were located. CW2 corroborated CW1's account, stating that John Frank, Eli Diacopolous, and Mark D'Angelo were the key individuals who communicated with the corporate leadership in the Netherlands.

415. Indeed, van Houten paid closed attention to Philips' Sleep and Respiratory Care business, including its ventilator business. Van Houten commented publicly about the number of individuals using the Dream devices, stated that "there is no concern on product quality," and even described the newly-introduced E30 ventilator as "safe and suitable for critical care." Van Houten scrutinized the Devices' performance and publicly touted that the Dream Stations were "driving

increased customer satisfaction and market share gains," demonstrating his familiarity with the Devices' quality, performance, and significant contributions to the Company's bottom line.

416. For example, on or around September 2020, van Houten became personally involved in discussions about a partial termination of a U.S. government contract to manufacture ventilators during Covid.[12] The U.S. government accused Philips of overcharging for the ventilators, an allegation that van Houten adamantly denied: "We can only guess that it has to do with the amount that has reached the stockpile . . . We have never overcharged."[13] Meanwhile, John Frank said the contract would not impact the Company's plan to move its space into a new building.[14]

417. Van Houten discussed the cancellation during an earnings call with investors, downplaying its impact. In response to an analyst's question, van Houten stated that "we had approximately 30,000, or so, ventilators in 2019 and a seven-fold increase this year, in which the cancellation of the 30,000 by the US takes a bite out of that. But it is still a very sizeable step-up versus 2019."

418. The seventh observation noted that "[p]rocedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established." Under the "Observation 7" header, the FDA reported many damaging findings, focusing on the fact that Philips had not been performing adequate quality control checks on the components of its Devices, including its Foam.

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[12] *See* https://www.bizjournals.com/pittsburgh/news/2020/09/10/philips-denying-claims-of-overpricing.html

[13] *Id.*

[14] *Id.*

419. Tellingly, and particularly damagingly, the FDA stated that Philips had "no established data, documentation, or written agreement that clearly describes or references the quality requirements of [its] raw foam supplier, or the specified requirements of the raw material components they supply, including raw foam components/materials."

420. The FDA found that this lack of standards had already come back to haunt Philips. A Supplier Corrective Action Request, initiated June 21, 2021, documented that an incorrect and non-specified polyester polyurethane, raw foam product resulted in non-conforming Trilogy Evo ventilatory finished Devices being approved, released, and distributed, which then had to be corrected. Philips had not documented previous "issues or concerns" with the foam supplier.

421. The eighth observation noted that "[p]otential consultants were not evaluated and selected based on their ability to meet specified requirements." Under the "Observation 8" header, the FDA reported "consultants were not evaluated and selected based on their ability to meet specified requirements, including quality requirements. Additionally, this firm did not evaluate, select, and approve these consultants, as approved suppliers before utilizing their consulting services on the quality issue of polyester polyurethane foam degradation and CAPA 7211." The FDA further stated that potential consultants did not even fill out Philips' required paperwork.

422. The FDA also expressed further concerns regarding the plan to replace the Foam in the recalled CPAP and BiPAP Devices with a different, silicone-based foam, a plan that had already begun being implemented. The November 12 FDA Update stated:

> Following the initial recall, Philips Respironics developed a plan to repair the polyester-based polyurethane foam in the recalled CPAP and BiPAP devices with a different, silicone-based foam. The FDA initially approved this plan based, in part, on testing the company provided to the FDA in June on the new foam.
>
> However, during the manufacturing facility inspection, the FDA obtained additional information, not previously available to the agency, regarding the silicone-based foam used in a singular, similar device marketed outside the U.S., which failed one safety test for the release of certain chemicals of concern, called

> volatile organic compounds (VOCs). Similar testing provided by Philips Respironics to the FDA on devices authorized for marketing in the U.S. had demonstrated acceptable results. The FDA has requested that Philips Respironics retain an independent laboratory to perform additional testing to determine what, if any, potential safety risks may be posed to patients by the silicone-based foam.

423. Philips issued a press release on November 14, 2021 stating that "[s]ince June 2021, Philips Respironics and certified testing laboratories have been conducting a comprehensive test and research program on the PE-PUR foam to better assess and scope potential patient health risks, with support from appropriately qualified third-party experts."

424. Van Houten is quoted in the press release as stating: "We will work closely with the FDA to clarify and follow up on the inspectional findings and its recent requests related to comprehensive testing. Until we have concluded these discussions, we are not able to publicly provide further details on these responses."

425. On the news of Philips' longstanding coverup, and the possible ineffectiveness of its replacement plan, Philips' stock price fell $5.46 per share, or 11.5%, to close at $42.16 per share on Monday, November 15, 2021.

426. Analysts immediately apprehended the devastating nature of the FDA's findings. On November 14, 2021, following a discussion with Company management about the FDA Report, Barclays published a Sunday report, concluding that Company "management's awareness of potential foam degradation issues well in advance of corrective actions" raises "further questions around the quality management processes at Philips," thus weighing on the value of the Company's securities. Barclays stated it "await[ed] more detail" from Philips in the form of the FDA-mandated test results of the DreamStation, "anticipated later this quarter."

427. Also on November 14, 2021, J.P. Morgan published a report concluding that the issues raised in the FDA Report are "likely to raise perceived risk" of investing in the Company's securities. J.P. Morgan noted that the FDA has asked the Company for independent test results of

the silicone foam that is "being used in DreamStation 2 and in the repair/replace programme to replace the original polyurethane foam." The report posits that "a negative outcome on further testing on the DreamStation foam degradation" is a downside risk, while "a positive outcome on further testing on the DreamStation foam degradation" is an upside risk.

428. On November 15, 2021, Deutsche Bank published a report attributing the November 15, 2021 share price decline to "the FDA's publication of its 483 form submission to Philips," which "only added to the uncertainty surrounding the sleep care product recall." The Report noted that "Philips may have known about the deficiencies for several years" as one of the self-explanatory reasons for the "share price reaction." The Report also noted that Philips is currently conducting independent testing that "aim[s] to determine the level of health risks (incl. potential carcinogenic effects) for patients that used the devices" subject to the June 14, 2021 recall, "and they should greatly impact the potential extent of litigation. These test results are still expected to be announced in 4Q21." The Report concluded that [i]n light of all of these uncertainties around the recall and the potential extent of litigation, [Deutsche Bank] continue[s] to find it difficult to get excited about" investing in the Company.

429. On November 19, 2021, following a discussion with Company management, Barclays published another report concluding that there remains "some uncertainty ahead of the detailed [DreamStation] results later this quarter."

430. On December 23, 2021, Philips issued a press release to update the public about testing of only the first-generation DreamStation devices. In relevant part, the release downplayed the long-term health impact of the devices:

> Review of this assessment by an outside medical panel and Philips Respironics has determined that exposure to the level of VOCs identified to date for the first-generation DreamStation devices is not typically anticipated to result in long-term health consequences for patients:

> The update on these findings is intended to inform healthcare providers of the most recent data, but the overall guidance for physicians and patients in the recall notification remains unchanged at this time.
>
> At the time the recall notification was issued, Philips Respironics relied on an initial, limited data set and toxicological risk assessment. Since then, using ISO 18562 guidance, VOC toxicological risk assessments were performed by certified testing laboratories and a qualified third-party expert based on the initial and new VOC testing performed to date. Philips Respironics has made this data available to the FDA and other competent authorities and is in the process of sharing this data with healthcare providers and patients.

Philips again implied that ozone cleaners were to blame for earlier issues, stating: "It is important to note that the tested DreamStation devices were not exposed to ozone cleaning, in accordance with the instructions for use."

431. On December 21, 2021, Philips recalled certain Trilogy Evo ventilators for potential health risks from the PE-PUR foam.

432. On January 26, 2022, the FDA labeled Philips expanded ventilator recall, which related to certain Trilogy Evo ventilators, as Class I, the most serious level recall.

433. On this news, Philips' stock price fell $0.96 per share, or 2.90%, to close at $32.20 per share on January 26, 2022.

434. On February 14, 2022, Connecticut's U.S. Senator Richard Blumenthal and Attorney General William Tong sent a letter to the FDA's Commissioner stating that "Connecticut constituents have expressed alarm that the FDA and Philips have failed to put in place a transparent plan to mitigate the now-clear carcinogenic risks associated with these devices, despite multiple warnings to consumers." On February 14, 2022, Senator Blumenthal also tweeted: "Philips' breathing machine recall process has been a deeply inadequate, life threatening failure. I join @AGWilliamTong to demand the FDA act swiftly to hold Philips accountable [and] protect the millions of Americans [and] thousands of CT residents impacted by this recall."

435. On this news, Philips' stock price fell $0.63 per share, or 1.87%, to close at $33.03 per share on February 14, 2022.

436. On March 10, 2022, the FDA issued a notification order to Philips Respironics requiring it to notify patients and others of the June 14, 2021 recall. The FDA had received numerous calls from patients and consumers who reported problems and concerns regarding the recalled ventilators, but were unaware of the recall and had not been informed by Philips of the health risks presented by the recalled ventilators. The FDA stated that "it is likely that a significant portion of patients and consumers using the Recalled Products are unaware of the health risks presented by those products." The FDA explained that the agency issued the order due to a "significant period of time that has transpired since the initiation of the recall, and Philips' failure to timely provide effective notice to health professionals who prescribe or use the Recalled Products and other persons (including consignees, distributors, retailers, and device users) who should be notified, of the recall and the health risks presented by the Recalled Products." The FDA also stated that it "has concerns that Philips has not, and is not, providing patients and consumers with sufficient information regarding the progress of the recall and the process for obtaining a replacement device."

437. On this news, Philips' stock price fell $0.61 per share, or 1.93%, to close at $31.02 per share on March 10, 2022.

438. On April 25, 2022, Philips announced that Philips Respironics and other unnamed Philips subsidiaries in the United States received criminal subpoenas on April 8, 2022 from the U.S. Department of Justice, seeking "information related to events leading to the Respironics [foam] recall." "At this time, it's a subpoena for information," van Houten said during an April 25, 2022 earnings call. "That means they are preparing an investigation, and we just have to accept

that." Van Houten was asked about his expectations of further action from regulatory agencies, such as warning letters, a consent decree, and potential fines, to which he replied, in part, that "I don't exclude anything." The same day, Philips also announced that the completion of the recall would be delayed and that the Company would be taking another provision of Euro 165 million for the recall, not including potential legal or regulatory costs.

439. On this news, Philips' stock price fell $3.43 per share, or 11.3%, to close at $26.91 per share on April 25, 2022.

440. On June 28, 2022, Philips' shares dropped approximately 3.18%, to close at $21.29 per share on June 28, 2022, after analysts from UBS said on that day that tests from the Company's first-generation DreamStation devices were not reassuring to the market. Citing the failure of two cytotoxicity tests, UBS called it a "'disappointing testing update' and not the 'unequivocal' positive news investors were hoping for."

441. During a July 25, 2022 earnings call with investors, Philips stated that the DOJ provided a proposed consent decree in relation to the FDA's inspection of Philips Respironics facilities in 2021. While the terms of the proposed consent decree were not disclosed, Wall Street analysts were already weighing in on the DOJ news, arguing that it will likely boost rival ResMed, if the FDA temporarily shuts Philips' manufacturing. "The consent decree could lead to production being stopped at [Philips] facilities while it resolves its quality issues, causing further delays in re-entering the market," Needham analysts wrote in a Monday note. Analysts with KeyBanc Capital Markets wrote that a consent decree "would present additional uncertainty to its ability to fully return to new patient diagnosis."

442. On this news, Philips' stock price fell $1.59 per share, or 7.18%, to close at $20.55 per share on July 25, 2022.

443. A leading medical publication, *MedTech Dive,* commented: "Philips said it is in talks with the DOJ, on behalf of the FDA, regarding 'the terms of a proposed consent decree to resolve the identified issues.' The company's stock price fell nearly 7%." Needham analysts wrote that "[t]he consent decree could lead to production being stopped at [Philips] facilities while it resolves its quality issues, causing further delays in re-entering the market. However, we think that the FDA/DOJ may try to avoid this given the severe flow generator shortage and patient backlog." Analysts with KeyBanc Capital Markets wrote that a consent decree "would present additional uncertainty to [the Company's] ability to fully return to new patient diagnosis."

444. On August 16, 2022, Philips announced a change in leadership, with van Houten stepping down from his role as CEO of the Company. The FDA also updated its safety communication concerning the breakdown of the Foam in the recalled Devices. Since April 2021, the FDA has received more than 69,000 MDRs, including 168 reports of death, associated with the Foam breakdown or suspected Foam breakdown.

445. On this news, Philips' stock price fell $1.11 per share, or 5.4%, to close at $19.48 per share on August 17, 2022.

446. On October 12, 2022, Philips stated that it "expects to record a 1.3 billion euro [$1.26 billion] non-cash charge in the third quarter for the impairment of goodwill of its sleep and respiratory care business." Philips also stated that it expects third-quarter group sales to be approximately €4.3 billion with a comparable sales decline of approximately 5%. Because of lower sales, Group Adjusted EBITA for the quarter is expected to be €210 million. The Company represented that "[t]he drivers for the revised forecast include current assumptions regarding the estimated impact of the proposed consent decree and changes to the pre-tax discount rate."

447. On this news, Philips' stock price fell 11.7%, to close at $13.17 per share on October 12, 2022.

448. ING analyst Marc Hesselink stated "[t]his weakness will also spill into 2023 where consensus on adjusted EBITA probably also needs to come down by at least 10%. Next step will be the 2025 targets which became very challenging especially now that the Sleep & Respiratory care business is not expected to fully recover post the recall."

449. On October 13, 2022, Societe Generale analysts downgraded Philips stock to hold from buy citing the company's recent profit warning and less confidence that the company will experience a recovery next year. On October 14, 2022, Deutsche Bank analyst Falko Friedrichs downgraded the stock to sell, stating that there are significant risks on the horizon, given the "surprising magnitude" of the Company's profit warning.

450. On October 24, 2022, Philips announced that it would cut 4,000 jobs (about 5% of Philips' workforce) as part of a EU300 million cost savings package for the June 14, 2021 recall. A *Bloomberg* article stated "shares in Philips fall as much as 4%, to their lowest since 2011, after saying it would cut 4,000 jobs as part of a EU300 million cost savings package, which analysts say may imply liquidity problems for the Dutch medical technology firm." Philips' new CEO, Roy Jakobs, admitted that the Company had to "rebuilt trust" and had not "lived up to . . . expectations" of its shareholders in recent years.

451. On this news, Philips' stock price fell $0.18 per share, or 1.4%, to close at $12.89 per share on October 24, 2022.

452. On October 31, 2022, pre-market, J.P. Morgan issued an analyst report cutting and moving the price target for Philips as part of their "feedback, latest thoughts and model update" following the Company's investor meeting held on October 28. J.P. Morgan stated that "[t]here

remain significant overhangs around litigation, supply chain, the macro outlook and their new mid-term outlook from a new CEO." J.P. Morgan explained that free cash flow was "being impacted by the high restructuring and recall costs," and that "[t]he company has flagged quality issues and supply chain disruptions as on-going concerns." As for biocompatibility study results, the analysts expressed disappointment in the unexpected delays of the outcomes from the testing studies, which "may increase investor nervousness."

453. On this news, Philips' stock price fell $0.45 per share, or 3.5%, to close at $12.58 per share on November 2, 2022. The next day, on November 3, 2022, Philips' stock price fell another $0.83 per share, or 6.6%, to close at $11.75 per share.

454. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiffs and other Class members have suffered significant losses and damages.

455. On August 16, 2022, the FDA updated its safety communication concerning the breakdown of the Foam in the recalled ventilators. Specifically, since April 2021, the FDA has received more than 69,000 MDRs, including 168 reports of death, associated with the Foam breakdown or suspected Foam breakdown. Then, from May 1, 2022, through July 31, 2022, the FDA received more than 48,000 MDRs, including 44 reports of death, associated with the Foam breakdown or suspected foam breakdown. A wide range of injuries has been reported in these MDRs, including cancer, pneumonia, asthma, other respiratory problems, infection, headache, cough, dyspnea (difficulty breathing), dizziness, nodules, and chest pain.

456. Users bringing lawsuits against Philips have alleged they developed multiple types of cancers as a result of their use of the Devices, including Bladder Cancer, Brain Cancer, Breast Cancer, Emphysema, Kidney Cancer, Leukemia, Liver Cancer, Lung Cancer, Lymphatic Cancer,

Multiple Myeloma, Oropharyngeal Cancer, Papillary Carcinoma, Pulmonary Fibrosis, non-Hodgkin lymphoma, Prostate Cancer, Stomach Cancer and Thyroid Cancer. The chemicals in the Foam include isocyanates, some of which are compounds classified as potential human carcinogens and known to cause cancer in animals, according to the Occupational Safety and Health Administration. Organ cancers are of particular risk with the relevant chemicals. They also cause asthma and lung problems and may have additional impact on the eyes, nose, throat and skin.

457. To date, there are approximately 60,000 personal injury cases consolidated in a multi-district litigation in the United States, alleging a wide range of health conditions including cancer, chronic obstructive pulmonary disease, and kidney disease, as well as heart and lung injuries from using ventilators and sleep apnea devices with the Foam.[15]

458. There are at least 5.5 million affected Devices globally. About half of the Devices are in the United States.

PLAINTIFFS' CLASS ACTION ALLEGATIONS

459. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Philips securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

[15] *In re Philips Recalled CPAP, BI-LEVEL PAP, and Mechanical Ventilator Products Litigation*, No. 21-mc-1230, MDL No. 3014 (W.D. Pa. July 6, 2022).

460. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Philips securities were actively traded on the NYSE. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Philips or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

461. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

462. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

463. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Philips;
- whether the Individual Defendants caused Philips to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

- whether the prices of Philips securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

464. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

465. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Philips securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NYSE and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiffs and members of the Class purchased, acquired and/or sold Philips securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

466. Based upon the foregoing, Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

467. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material

information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

NO SAFE HARBOR

468. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the false or misleading statements pleaded herein. The statements alleged to be false or misleading herein all relate to then-existing facts and conditions. Additionally, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified specifically as "forward-looking statements" when made, the statements were unaccompanied by specific or meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

469. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those forward-looking statements because at the time each such statement was made, the speaker had actual knowledge, or recklessly disregarded the risk, that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Philips who knew, or recklessly disregarded the risk, that the statement was false when it was made.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

470. Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

471. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

472. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiffs and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Philips securities; and (iii) cause Plaintiffs and other members of the Class to purchase or otherwise acquire Philips securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

473. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Philips securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Philips' finances and business prospects.

474. By virtue of their positions at Philips, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiffs and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

475. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Philips, the Individual Defendants had knowledge of the details of Philips' internal affairs.

476. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Philips. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Philips' businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Philips securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Philips' business and financial condition which were concealed by Defendants, Plaintiffs and the other members of the Class purchased or otherwise acquired Philips securities at

artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

477. During the Class Period, Philips' securities were traded on an active and efficient market. Plaintiffs and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Philips securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiffs and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiffs and the Class, the true value of Philips' securities was substantially lower than the prices paid by Plaintiffs and the other members of the Class. The market price of Philips' securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiffs and Class members.

478. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

479. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

480. Plaintiffs repeat and re-allege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

481. During the Class Period, the Individual Defendants participated in the operation and management of Philips, and conducted and participated, directly and indirectly, in the conduct of Philips' business affairs. Because of their senior positions, they knew the adverse non-public information about Philips' misstatement of income and expenses and false financial statements.

482. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Philips' financial condition and results of operations, and to correct promptly any public statements issued by Philips, which had become materially false or misleading.

483. Van Houten was Philips' Chief Executive Officer and Chairman of the Board of Management and the Executive Committee at all relevant times and frequently spoke on behalf of the Company. Bhattacharya was a Member of the Executive Committee at all relevant times, Chief Financial Officer since October 12, 2015, and a Member of the Board of Management since December 18, 2015. He, too, frequently spoke on behalf of the Company.

484. As documented above, each was at meetings about quality control during the Class Period.

485. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings, which Philips disseminated in the marketplace during the Class Period concerning Philips' results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Philips to engage in the wrongful acts complained of herein.

The Individual Defendants, therefore, were "controlling persons" of Philips within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Philips' securities.

486. Each of the Individual Defendants, therefore, acted as a controlling person of Philips. By reason of their senior management positions and/or being directors of Philips, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Philips to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Philips and possessed the power to control the specific activities, which comprise the primary violations about which Plaintiffs and the other members of the Class complain.

487. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Philips.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiffs as the Class representatives;

B. Requiring Defendants to pay damages sustained by Plaintiffs and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiffs and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiffs hereby demand a trial by jury.

Dated: November 30, 2022 Respectfully submitted,

POMERANTZ LLP

/s/ Emma Gilmore

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